ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Loxicom 0.5 mg/ml oral suspension for dogs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance:
Meloxicam 0.5 mg

Excipients:
Sodium benzoate 1.5 mg

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Oral suspension.
Pale yellow suspension.

4. CLINICAL PARTICULARS

4.1 Target species

Dogs.

4.2 Indications for use, specifying the target species

Alleviation of inflammation and pain in both acute and chronic musculo-skeletal disorders in dogs.

4.3 Contraindications

Do not use in pregnant or lactating animals.
Do not use in dogs suffering from gastrointestinal disorders such as irritation and haemorrhage, impaired hepatic, cardiac or renal function and haemorrhagic disorders.
Do not use in case of hypersensitivity to the active substance or to any of the excipients.
Do not use in dogs less than 6 weeks of age.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

Special precautions for use in animals

If adverse reactions occur, treatment should be discontinued and the advice of a veterinarian should be sought.
Avoid use in any dehydrated, hypovolaemic or hypotensive animal, as there is a potential risk of renal toxicity.

This product for dogs should not be used in cats due to the different dosing devices. In cats, Loxicom 0.5 mg/ml oral suspension for cats should be used.

Special precautions to be taken by the person administering the veterinary medicinal product to animals

People with known hypersensitivity to non-steroidal anti-inflammatory drugs (NSAIDs) should avoid contact with the veterinary medicinal product.
In case of accidental ingestion, seek medical advice immediately and show the package leaflet or the label to the physician.

4.6 Adverse reactions (frequency and seriousness)

Typical adverse reactions of NSAIDs such as loss of appetite, vomiting, diarrhoea, faecal occult blood, apathy and renal failure have occasionally been reported. In very rare cases, haemorrhagic diarrhoea, haematemesis, gastrointestinal ulceration and elevated liver enzymes have been reported. These adverse reactions occur generally within the first treatment week and are in most cases transient and disappear following termination of the treatment but in very rare cases may be serious or fatal.
If adverse reactions occur, treatment should be discontinued and the advice of a veterinarian should be sought.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reactions)
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

4.7 Use during pregnancy, lactation or lay

The safety of the veterinary medicinal product has not been established during pregnancy and lactation (see section 4.3).

4.8 Interaction with other medicinal products and other forms of interaction

Other NSAIDs, diuretics, anticoagulants, aminoglycoside antibiotics and substances with high protein binding may compete for binding and thus lead to toxic effects. Loxicom must not be administered in conjunction with other NSAIDs or glucocorticosteroids.

Pre-treatment with other anti-inflammatory substances may result in additional or increased adverse effects and accordingly a treatment-free period with such veterinary medicinal products should be observed for at least 24 hours before commencement of treatment. The treatment-free period, however, should take into account the pharmacokinetic properties of the products used previously.

4.9 Amounts to be administered and administration route

Oral use.

Initial treatment is a single dose of 0.2 mg meloxicam/kg bodyweight (i.e. 4 ml/10 kg bodyweight) on the first day. Treatment is to be continued once daily by oral administration (at 24 hour intervals) at a maintenance dose of 0.1 mg meloxicam/kg bodyweight (i.e. 2 ml/10 kg bodyweight).

For longer term treatment, once clinical response has been observed (after $\geq$ 4 days), the dose can be adjusted to the lowest effective individual dose reflecting that the degree of pain and inflammation associated with chronic musculo-skeletal disorders may vary over time.

Particular care should be taken with regard to the accuracy of dosing.
The suspension can be given using either of the two measuring syringes provided in the package. The syringes fit onto the bottle and have a kg-bodyweight scale which corresponds to the maintenance dose (i.e. 0.1 mg meloxicam/kg bodyweight). Thus for the first day, twice the maintenance volume will be required. Alternatively therapy may be initiated with Loxicom 5 mg/ml solution for injection.

A clinical response is normally seen within 3-4 days. Treatment should be discontinued after 10 days at the latest if no clinical improvement is apparent.

Advice on correct administration
To be administered with food or directly into the mouth.
Shake well before use.
Avoid introduction of contamination during use.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

In the case of overdose, symptomatic treatment should be initiated.

4.11 Withdrawal period(s)

Not applicable.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic Group: Anti-inflammatory and anti-rheumatic products, non-steroids (oxicams).
ATCvet code: QM01AC06

5.1 Pharmacodynamic properties

Meloxicam is a non-steroidal anti-inflammatory drug (NSAID) of the oxicam class which acts by inhibition of prostaglandin synthesis, thereby exerting anti-inflammatory, analgesic, anti-exudative and antipyretic effects. It reduces leukocyte infiltration into the inflamed tissue. To a minor extent it also inhibits collagen-induced thrombocyte aggregation. *In vitro* and *in vivo* studies demonstrated that meloxicam inhibits cyclooxygenase-2 (COX-2) to a greater extent than cyclooxygenase-1 (COX-1).

5.2 Pharmacokinetic particulars

Absorption
Meloxicam is completely absorbed following oral administration and maximal plasma concentrations are obtained after approximately 4.5 hours. When the product is used according to the recommended dosage regime, steady state concentrations of meloxicam in plasma are reached on the second day of treatment.

Distribution
There is a linear relationship between the dose administered and plasma concentration observed in the therapeutic dose range. Approximately 97 % of meloxicam is bound to plasma proteins. The volume of distribution is 0.3 l/kg.

Metabolism
Meloxicam is predominantly found in plasma and is also a major biliary excretion product whereas urine contains only traces of the parent compound. Meloxicam is metabolised to an alcohol, an acid derivative and to several polar metabolites. All major metabolites have been shown to be pharmacologically inactive.

Elimination
Meloxicam is eliminated with a half-life of 24 hours. Approximately 75 % of the administered dose is eliminated via faeces and the remainder via urine.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium benzoate
Glycerol
Povidone K30
Xanthan gum
Disodium phosphate dihydrate
Sodium dihydrogen phosphate dihydrate
Citric acid anhydrous
Simethicone emulsion
Purified water

6.2 Major incompatibilities

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

6.3 Shelf-life

Shelf-life of the veterinary medicinal product as packaged for sale: 18 months
Shelf-life after first opening the immediate packaging: 6 months

6.4 Special precautions for storage

This veterinary medicinal product does not require any special storage conditions.

6.5 Nature and composition of immediate packaging

The veterinary medicinal product is presented in 15 ml and 30 ml polyethylene terephthalate screw bottles with HDPE/LDPE child resistant caps. Two polyethylene/polypropylene measuring syringes, a 1 ml and a 5 ml syringe, are supplied with each bottle to ensure accurate dosing of small and large dogs. Each syringe is graduated in bodyweight, the 1 ml syringe is graduated from 0.25 kg to 5.0 kg and the 5 ml syringe for 1 kg to 25 kg.

Not all pack sizes may be marketed.

6.6 Special precautions for the disposal of unused veterinary medicinal product or waste material derived from the use of such products

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

Norbrook Laboratories (Ireland) Limited
Rossmore Industrial Estate

Monaghan
Ireland

8. MARKETING AUTHORISATION NUMBER

EU/2/08/090/001
EU/2/08/090/002

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 10/02/2009
Date of last renewal: 23/01/2019

10. DATE OF REVISION OF THE TEXT

Detailed information on this veterinary medicinal product is available on the website of the European Medicines Agency http://www.ema.europa.eu/.

PROHIBITION OF SALE, SUPPLY AND/OR USE

Not applicable.

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Loxicom 1.5 mg/ml oral suspension for dogs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active Substance:
Meloxicam 1.5 mg

Excipients:
Sodium Benzoate 1.5 mg

For the full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Oral suspension
Pale yellow suspension.

4. CLINICAL PARTICULARS

4.1 Target species

Dogs.

4.2 Indications for use, specifying the target species

Alleviation of inflammation and pain in both acute and chronic musculo-skeletal disorders in dogs.

4.3 Contraindications

Do not use in pregnant or lactating animals.
Do not use in animals suffering from gastrointestinal disorders such as irritation and haemorrhage, impaired hepatic, cardiac or renal function and haemorrhagic disorders.
Do not use in case of hypersensitivity to the active substance or to any of the excipients.
Do not use in dogs less than 6 weeks of age.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

Special precautions for use in animals

If adverse reactions occur, treatment should be discontinued and the advice of a veterinarian should be sought.
Avoid use in any dehydrated, hypovolaemic or hypotensive animal, as there is a potential risk of renal toxicity.

Special precautions to be taken by the person administering the veterinary medicinal product to animals

People with known hypersensitivity to non-steroidal anti-inflammatory drugs (NSAIDs) should avoid contact with the veterinary medicinal product.
In case of accidental ingestion, seek medical advice immediately and show the package leaflet or the label to the physician.

4.6 Adverse reactions (frequency and seriousness)

Typical adverse reactions of NSAIDs such as loss of appetite, vomiting, diarrhoea, faecal occult blood, apathy and renal failure have occasionally been reported. In very rare cases haemorrhagic diarrhoea, haematemesis, gastrointestinal ulceration and elevated liver enzymes have been reported. These adverse reactions occur generally within the first treatment week and are in most cases transient and disappear following termination of the treatment but in very rare cases may be serious or fatal.
If adverse reactions occur, treatment should be discontinued and the advice of a veterinarian should be sought.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reactions)
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

4.7 Use during pregnancy, lactation or lay

The safety of the veterinary medicinal product has not been established during pregnancy and lactation (see section 4.3).

4.8 Interaction with other medicinal products and other forms of interaction

Other NSAIDs, diuretics, anticoagulants, aminoglycoside antibiotics and substances with high protein binding may compete for binding and thus lead to toxic effects. Loxicom must not be administered in conjunction with other NSAIDs or glucocorticosteroids.

Pre-treatment with anti-inflammatory substances may result in additional or increased adverse effects and accordingly a treatment-free period with such veterinary medicinal products should be observed for at least 24 hours before commencement of treatment. The treatment-free period, however, should take into account the pharmacokinetic properties of the products used previously.

4.9 Amounts to be administered and administration route

Oral use.

Initial treatment is a single dose of 0.2 mg meloxicam/kg bodyweight (i.e. 1.33 ml/10 kg bodyweight) on the first day. Treatment is to be continued once daily by oral administration (at 24 hour intervals) at a maintenance dose of 0.1 mg meloxicam/kg bodyweight (i.e. 0.667 ml/10 kg bodyweight).

For longer term treatment, once clinical response has been observed (after ≥ 4 days), the dose can be adjusted to the lowest effective individual dose reflecting that the degree of pain and inflammation associated with chronic musculo-skeletal disorders may vary over time.

Particular care should be taken with regard to the accuracy of dosing.

The suspension can be given using either of the two measuring syringes provided in the package (depending on weight of dog). The syringes fit onto the bottle and have a kg-bodyweight scale which corresponds to the maintenance dose (i.e. 0.1 mg meloxicam/kg bodyweight). Thus for the first day, twice the maintenance volume will be required. Alternatively therapy may be initiated with Loxicom 5 mg/ml solution for injection.

A clinical response is normally seen within 3-4 days. Treatment should be discontinued after 10 days at the latest if no clinical improvement is apparent.

To be administered with food or directly into the mouth.
Shake well before use.
Avoid introduction of contamination during use.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

In the case of overdose, symptomatic treatment should be initiated.

4.11 Withdrawal period(s)

Not applicable.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic Group: Anti-inflammatory and anti-rheumatic products, non-steroids (oxicams).
ATCvet code: QM01AC06

5.1 Pharmacodynamic properties

Meloxicam is a non-steroidal anti-inflammatory drug (NSAID) of the oxicam class which acts by inhibition of prostaglandin synthesis, thereby exerting anti-inflammatory, analgesic, anti-exudative and antipyretic effects. It reduces leukocyte infiltration into the inflamed tissue. To a minor extent it also inhibits collagen-induced thrombocyte aggregation. *In vitro* and *in vivo* studies demonstrated that meloxicam inhibits cyclooxygenase-2 (COX-2) to a greater extent than cyclooxygenase-1 (COX-1).

5.2 Pharmacokinetic particulars

Absorption
Meloxicam is completely absorbed following oral administration and maximal plasma concentrations are obtained after approximately 4.5 hours. When the product is used according to the recommended dosage regime, steady state concentrations of meloxicam in plasma are reached on the second day of treatment.

Distribution
There is a linear relationship between the dose administered and plasma concentration observed in the therapeutic dose range in dogs. Approximately 97 % of meloxicam is bound to plasma proteins. The volume of distribution is 0.3 l/kg.

Metabolism
Meloxicam is predominantly found in plasma and is also a major biliary excretion product whereas urine contains only traces of the parent compound. Meloxicam is metabolised to an alcohol, an acid derivative and to several polar metabolites. All major metabolites have been shown to be pharmacologically inactive.

Elimination
Meloxicam is eliminated with a half-life of 24 hours. Approximately 75 % of the administered dose is eliminated via faeces and the remainder via urine.

6. PHARMACEUTICAL PARTICULARS

6.1 List of Excipients

Sodium benzoate
Glycerol
Povidone K30
Xanthan gum
Disodium phosphate dihydrate
Sodium dihydrogen phosphate dihydrate
Citric acid anhydrous
Simethicone emulsion
Purified water

6.2 Major incompatibilities

None known.

6.3 Shelf-life

Shelf-life of the veterinary medicinal product as packaged for sale: 18 months
Shelf-life after first opening the immediate packaging: 6 months

6.4 Special precautions for storage

This veterinary medicinal product does not require any special storage conditions.

6.5 Nature and composition of immediate packaging

The veterinary medicinal product is presented in 10 ml, 32 ml, 100 ml, 2 x 100 ml and 200 ml polyethylene terephthalate screw bottles with HDPE/LDPE child resistant caps. Two polyethylene/polypropylene measuring syringes, a 1 ml and 5 ml syringe, are supplied with each bottle to ensure accurate dosing of small and large dogs. Each syringe is graduated in bodyweight, the 1 ml syringe is graduated from 0.5 kg to 15 kg and the 5 ml syringe for 2.5 kg to 75 kg.

Not all pack sizes may be marketed.

6.6 Special precautions for the disposal of unused veterinary medicinal product or waste material derived from the use of such products

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

Norbrook Laboratories (Ireland) Limited
Rossmore Industrial Estate
Monaghan
Ireland

8. MARKETING AUTHORISATION NUMBER(S)

EU/2/08/090/003
EU/2/08/090/004
EU/2/08/090/005
EU/2/08/090/032
EU/2/08/090/033

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 10/02/2009
Date of last renewal: 23/01/2019

10. DATE OF REVISION OF THE TEXT

Detailed information on this veterinary medicinal product is available on the website of the European Medicines Agency http://www.ema.europa.eu/.

PROHIBITION OF SALE, SUPPLY AND/OR USE

Not applicable.

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Loxicom 5 mg/ml solution for injection for dogs and cats.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active Substance:
Meloxicam 5 mg

Excipients:
Ethanol, anhydrous 150 mg

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Solution for injection
Pale yellow solution.

4. CLINICAL PARTICULARS

4.1 Target species

Dogs and cats.

4.2 Indications for use, specifying the target species

Dogs:
Alleviation of inflammation and pain in both acute and chronic musculo-skeletal disorders. Reduction of post-operative pain and inflammation following orthopaedic and soft tissue surgery.

Cats:
Reduction of post-operative pain after ovariohysterectomy and minor soft tissue surgery.

4.3 Contraindications

Do not use in pregnant or lactating animals.
Do not use in animals suffering from gastrointestinal disorders such as irritation and haemorrhage, impaired hepatic, cardiac or renal function and haemorrhagic disorders.
Do not use in case of hypersensitivity to the active substance or to any of the excipients.
Do not use in animals less than 6 weeks of age nor in cats of less than 2 kg.

4.4 Special warnings for each target species

For post-operative pain relief in cats, safety has only been documented after thiopental/halothane anaesthesia.

4.5 Special precautions for use

Special precautions for use in animals

If adverse reactions occur, treatment should be discontinued and the advice of a veterinarian should be sought.
Avoid use in any dehydrated, hypovolaemic or hypotensive animal, as there is a potential risk of renal toxicity.
During anaesthesia, monitoring and fluid therapy should be considered as standard practice.

Special precautions to be taken by the person administering the veterinary medicinal product to animals

Accidental self-injection may give rise to pain. People with known hypersensitivity to NSAIDs should avoid contact with the veterinary medicinal product.
In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.

4.6 Adverse reactions (frequency and seriousness)

Typical adverse reactions of NSAIDs such as loss of appetite, vomiting, diarrhoea, faecal occult blood, apathy and renal failure have occasionally been reported. In very rare cases elevated liver enzymes have been reported.

In very rare cases, haemorrhagic diarrhoea, haematemesis and gastrointestinal ulceration have been reported.

These adverse reactions occur generally within the first treatment week and are in most cases transient and disappear following termination of the treatment but in very rare cases may be serious or fatal.

In very rare cases anaphylactoid reactions may occur and should be treated symptomatically.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports)

4.7 Use during pregnancy, lactation or lay

The safety of the veterinary medicinal product has not been established during pregnancy and lactation (see section 4.3).

4.8 Interaction with other medicinal products and other forms of interaction

Other NSAIDs, diuretics, anticoagulants, aminoglycoside antibiotics and substances with high protein binding may compete for binding and thus lead to toxic effects. Loxicom must not be administered in conjunction with other NSAIDs or glucocorticosteroids. Concurrent administration of potential nephrotoxic drugs should be avoided. In animals at anaesthetic risk (e.g. aged animals) intravenous or subcutaneous fluid therapy during anaesthesia should be taken into consideration. When anaesthesia and NSAID are concomitantly administered, a risk for renal function cannot be excluded.

Pre-treatment with other anti-inflammatory substances may result in additional or increased adverse effects and accordingly a treatment-free period with such drugs should be observed for at least 24

hours before commencement of treatment. The treatment-free period, however, should take into account the pharmacokinetic properties of the products used previously.

4.9 Amounts to be administered and administration route

Dogs:
Musculo-skeletal disorders: Single subcutaneous injection at a dosage of 0.2 mg meloxicam/kg bodyweight (i.e. 0.4 ml/10 kg bodyweight). Loxicom 1.5 mg/ml oral suspension and Loxicom 0.5 mg/ml oral suspension may be used for continuation of treatment at a dosage of 0.1 mg meloxicam/kg bodyweight, 24 hours after administration of the injection.

Reduction of post-operative pain (over a period of 24 hours): Single intravenous or subcutaneous injection at a dosage of 0.2 mg meloxicam/kg bodyweight (i.e. 0.4 ml/10 kg bodyweight) before surgery, for example at the time of induction of anaesthesia.

Cats:
Reduction of post-operative pain in cats where no oral follow-up treatment is possible e.g. feral cats: Single subcutaneous injection at a dosage of 0.3 mg meloxicam/kg bodyweight (i.e. 0.06 ml/kg bodyweight) before surgery, for example at the time of induction of anaesthesia. In this case do not use oral follow up treatment.

Reduction of post-operative pain in cats when administration of meloxicam is to be continued as an oral follow-up therapy:
Single subcutaneous injection at a dosage of 0.2 mg meloxicam/kg body weight (i.e. 0.04 ml/kg body weight) before surgery, for example at the time of induction of anaesthesia.
To continue treatment for up to five days, this initial dose may be followed 24 hours later by administration of Loxicom 0.5 mg/ml oral suspension for cats at a dosage of 0.05 mg meloxicam/kg body weight. The oral follow-up dose may be administered for up to a total of four doses at 24 hour intervals.

Particular care should be taken with regard to the accuracy of dosing.

A suitably graduated 1 ml syringe should be used for administration of the product to cats.

Avoid introduction of contamination during use.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

In the case of overdose, symptomatic treatment should be initiated.

4.11 Withdrawal period(s)

Not applicable.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic Group: Anti-inflammatory and anti-rheumatic products, non-steroids (oxicams).
ATCvet code: QM01AC06

5.1 Pharmacodynamic properties

Meloxicam is a non-steroidal anti-inflammatory drug (NSAID) of the oxicam class which acts by inhibition of prostaglandin synthesis, thereby exerting anti-inflammatory, analgesic, anti-exudative and antipyretic effects. It reduces leukocyte infiltration into the inflamed tissue. To a minor extent it

also inhibits collagen-induced thrombocyte aggregation. *In vitro* and *in vivo* studies demonstrated that meloxicam inhibits cyclooxygenase-2 (COX-2) to a greater extent than cyclooxygenase-1 (COX-1).

5.2 Pharmacokinetic particulars

Absorption
Following subcutaneous administration, meloxicam is completely bioavailable and maximal mean plasma concentrations of 0.73 µg/ml in dogs and 1.1 µg/ml in cats were reached approximately 2.5 hours and 1.5 hours post-administration, respectively.

Distribution
There is a linear relationship between the dose administered and plasma concentration observed in the therapeutic dose range in dogs. More than 97 % of meloxicam is bound to plasma proteins. The volume of distribution is 0.3 l/kg in dogs and 0.09 l/kg in cats.

Metabolism
In dogs, meloxicam is predominantly found in plasma and is also a major biliary excretion product whereas urine contains only traces of the parent compound. Meloxicam is metabolised to an alcohol, an acid derivative and to several polar metabolites. All major metabolites have been shown to be pharmacologically inactive.

Elimination
Meloxicam is eliminated with a half-life of 24 hours in dogs and 15 hours in cats. Approximately 75 % of the administered dose is eliminated via faeces and the remainder via urine.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Meglumine
Glycine
Ethanol (anhydrous)
Poloxamer 188
Sodium chloride
Glycofurol
Sodium hydroxide (for pH adjustment)
Hydrochloric acid (for pH adjustment)
Water for injection

6.2 Major incompatibilities

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

6.3 Shelf-life

Shelf-life of the veterinary medicinal product as packaged for sale: 3 years.
Shelf-life after first opening the immediate packaging: 28 days

6.4 Special precautions for storage

This veterinary medicinal product does not require any special storage conditions.

6.5 Nature and composition of immediate packaging

Colourless glass injection vial of 10, 20 or 100 ml, closed with a bromobutyl stopper and sealed with an aluminium cap.

Not all pack sizes may be marketed.

6.6 Special precautions for the disposal of unused veterinary medicinal product or waste material derived from the use of such products

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

Norbrook Laboratories (Ireland) Limited
Rossmore Industrial Estate
Monaghan
Ireland

8. MARKETING AUTHORISATION NUMBER(S)

EU/2/08/090/006
EU/2/08/090/007
EU/2/08/090/008

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 10/02/2009
Date of last renewal: 23/01/2019

10. DATE OF REVISION OF THE TEXT

Detailed information on this veterinary medicinal product is available on the website of the European Medicines Agency http://www.ema.europa.eu/.

PROHIBITION OF SALE, SUPPLY AND/OR USE

Not applicable.

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Loxicom 0.5 mg/ml oral suspension for cats

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active Substance:
Meloxicam 0.5 mg

Excipient:
Sodium benzoate 1.5 mg

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Oral suspension.
Pale yellow suspension.

4. CLINICAL PARTICULARS

4.1 Target species

Cats.

4.2 Indications for use, specifying the target species

Alleviation of mild to moderate post-operative pain and inflammation following surgical procedures in cats, e.g. orthopaedic and soft tissue surgery.
Alleviation of inflammation and pain in acute and chronic musculo-skeletal disorders in cats.

4.3 Contraindications

Do not use in pregnant or lactating cats.
Do not use in cats suffering from gastrointestinal disorders such as irritation and haemorrhage, impaired hepatic, cardiac or renal function and haemorrhagic disorders.
Do not use in case of hypersensitivity to the active substance or to any of the excipients
Do not use in cats less than 6 weeks of age.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

Special precautions for use in animals

If adverse reactions occur, treatment should be discontinued and the advice of a veterinarian should be sought.

Avoid use in any dehydrated, hypovolaemic or hypotensive animal, as there is a potential risk of renal toxicity.

Post-operative pain and inflammation following surgical procedures:
In case additional pain relief is required, multimodal pain therapy should be considered.

Chronic musculoskeletal disorders:
Response to long-term therapy should be monitored at regular intervals by a veterinary surgeon.

Special precautions to be taken by the person administering the veterinary medicinal product to animals

People with known hypersensitivity to non-steroidal anti-inflammatory drugs (NSAIDs) should avoid contact with the veterinary medicinal product.
In case of accidental ingestion, seek medical advice immediately and show the package leaflet or the label to the physician.

4.6 Adverse reactions (frequency and seriousness)

Typical adverse reactions of NSAIDs such as loss of appetite, vomiting, diarrhoea, faecal occult blood, lethargy and renal failure have occasionally been reported. Gastrointestinal ulceration and elevated liver enzymes were reported in very rare cases.

These adverse reactions occur generally within the first treatment week and are in most cases transient and disappear following termination of the treatment but in very rare cases may be serious or fatal.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reactions)
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

4.7 Use during pregnancy, lactation or lay

The safety of the veterinary medicinal product has not been established during pregnancy and lactation (see section 4.3).

4.8 Interaction with other medicinal products and other forms of interaction

Other NSAIDs, diuretics, anticoagulants, aminoglycoside antibiotics and substances with high protein binding may compete for binding and thus lead to toxic effects. Loxicom must not be administered in conjunction with other NSAIDs or glucocorticosteroids. Concurrent administration of potential nephrotoxic drugs should be avoided.

Pre-treatment with other anti-inflammatory substances may result in additional or increased adverse effects and accordingly a treatment-free period with such veterinary medicinal products should be observed for at least 24 hours before commencement of treatment. The treatment-free period, however, should take into account the pharmacological properties of the products used previously.

4.9 Amounts to be administered and administration route

Oral use.

Dosage

Post-operative pain and inflammation following surgical procedures:
After initial treatment with Loxicom 5 mg/ml solution for injection for dogs and cats continue treatment 24 hours later with Loxicom 0.5 mg/ml oral suspension for cats at a dosage of 0.05 mg meloxicam/kg body weight. The oral follow-up dose may be administered once daily (at 24-hour intervals) for up to four days.

Acute musculo-skeletal disorders:
Initial treatment is a single oral dose of 0.2 mg meloxicam/kg body weight on the first day. Treatment is to be continued once daily by oral administration (at 24-hour intervals) at a dose of 0.05 mg meloxicam/kg body weight for as long as acute pain and inflammation persist.

Chronic musculo-skeletal disorders:
Initial treatment is a single oral dose of 0.1 mg meloxicam/kg bodyweight on the first day. Treatment is to be continued once daily by oral administration (at 24 hour intervals) at a maintenance dose of 0.05 mg meloxicam/kg bodyweight.

A clinical response is normally seen within 7 days. Treatment should be discontinued after 14 days at the latest if no clinical improvement is apparent.

Route and method of administration
Dosing procedure:
The syringe fits onto the bottle and has a kg-body weight scale which corresponds to the maintenance dose of 0.05 mg meloxicam/kg body weight. Thus for initiation of the treatment of chronic musculo-skeletal disorders on the first day, twice the maintenance volume will be required. For initiation of the treatment of acute musculo-skeletal disorders on the first day, 4 times the maintenance volume will be required.

Particular care should be taken with regard to the accuracy of dosing. The recommended dose should not be exceeded. The suspension should be given using the Loxicom measuring syringe provided in the package.

Advice on correct administration
To be administered with food or directly into the mouth.
Shake well before use.
Avoid introduction of contamination during use.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

Meloxicam has a narrow therapeutic safety margin in cats and clinical signs of overdose may be seen at relatively small overdose levels. In the case of overdose, adverse reactions (as listed in Section 4.6) are expected to be more severe and more frequent. In the case of overdose symptomatic treatment should be initiated.

4.11 Withdrawal period(s)

Not applicable.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic Group: Anti-inflammatory and antirheumatic products, non-steroids (oxicams).
ATCvet code: QM01AC06

5.1 Pharmacodynamic properties

Meloxicam is a non-steroidal anti-inflammatory drug (NSAID) of the oxicam class which acts by inhibition of prostaglandin synthesis, thereby exerting anti-inflammatory, analgesic, anti-exudative and antipyretic effects. It reduces leukocyte infiltration into the inflamed tissue. To a minor extent it also inhibits collagen-induced thrombocyte aggregation. *In vitro* and *in vivo* studies demonstrated that meloxicam inhibits cyclooxygenase-2 (COX-2) to a greater extent than cyclooxygenase-1 (COX-1).

5.2 Pharmacokinetic particulars

Absorption
If the animal is fasted when dosed, the maximal plasma concentrations are obtained after approximately 3 hours. If the animal is fed at the time of dosing, the absorption may be slightly delayed. Due to the loading dose, steady state PK is reached after 2 days (48h).

Distribution
There is a linear relationship between the dose administered and plasma concentration observed in the therapeutic dose range. Approximately 97 % of meloxicam is bound to plasma proteins.

Metabolism
Meloxicam is predominantly found in plasma and is also a major biliary excretion product whereas urine contains only traces of the parent compound. Five major metabolites were detected all having been shown to be pharmacologically inactive. Meloxicam is metabolised to an alcohol, an acid derivative and to several polar metabolites. As for other species investigated, the main pathway of meloxicam biotransformation in cat is oxidation.

Elimination
Meloxicam is eliminated with a half-life of 24 hours. The detection of metabolites from the parent compound in urine and faeces, but not in plasma is indicative for their rapid excretion. 21 % of the recovered dose is eliminated in urine (2 % as unchanged meloxicam, 19 % as metabolites) and 79 % in the faeces (49 % as unchanged meloxicam, 30 % as metabolites).

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium benzoate
Glycerol
Povidone K30
Xanthan gum
Disodium phosphate dihydrate
Sodium dihydrogen phosphate dihydrate
Citric acid anhydrous
Simethicone emulsion
Purified water

6.2 Major incompatibilities

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

6.3 Shelf-life

Shelf-life of the veterinary medicinal product as packaged for sale: 18 months
Shelf-life after first opening the immediate packaging: 6 months

6.4 Special precautions for storage

This veterinary medicinal product does not require any special storage conditions.

6.5 Nature and composition of immediate packaging

The veterinary medicinal product is presented in 5 ml, 15 ml and 30 ml polyethylene terephthalate screw bottles with HDPE/LDPE child resistant caps. The 1 ml measuring polyethylene/polypropylene syringe has a kg-body weight scale for cats (0.5 to 10 kg).

Not all pack sizes may be marketed.

6.6 Special precautions for the disposal of unused veterinary medicinal product or waste material derived from the use of such products

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

Norbrook Laboratories (Ireland) Limited
Rossmore Industrial Estate
Monaghan
Ireland

8. MARKETING AUTHORISATION NUMBER

EU/2/08/090/009
EU/2/08/090/027
EU/2/08/090/028

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 10/02/2009
Date of last renewal: 23/01/2019

10. DATE OF REVISION OF THE TEXT

Detailed information on this veterinary medicinal product is available on the website of the European Medicines Agency http://www.ema.europa.eu/.

PROHIBITION OF SALE, SUPPLY AND/OR USE

Not applicable.

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Loxicom 20 mg/ml solution for injection for cattle, pigs and horses

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

One ml contains:

Active substance:
Meloxicam 20 mg

Excipient:
Ethanol 150 mg

For the full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Solution for injection.
A yellow solution.

4. CLINICAL PARTICULARS

4.1 Target species

Cattle, pigs and horses.

4.2 Indications for use, specifying the target species

Cattle:
For use in acute respiratory infection with appropriate antibiotic therapy to reduce clinical signs in cattle.
For use in diarrhoea in combination with oral re-hydration therapy to reduce clinical signs in calves of over one week of age and young, non-lactating cattle.
For adjunctive therapy in the treatment of acute mastitis, in combination with antibiotic therapy.
For the relief of post-operative pain following dehorning in calves.

Pigs:
For use in non-infectious locomotor disorders to reduce the symptoms of lameness and inflammation.
For adjunctive therapy in the treatment of puerperal septicaemia and toxaemia (mastitis-metritis-agalactia syndrome) with appropriate antibiotic therapy.

Horses:
For use in the alleviation of inflammation and relief of pain in both acute and chronic musculo-skeletal disorders.
For the relief of pain associated with equine colic.

4.3 Contraindications

See also section 4.7.
Do not use in horses less than 6 weeks of age.

Do not use in animals suffering from impaired hepatic, cardiac or renal function and haemorrhagic disorders, or where there is evidence of ulcerogenic gastrointestinal lesions.
Do not use in cases of hypersensitivity to the active substance or to any of the excipients.
For the treatment of diarrhoea in cattle, do not use in animals of less than one week of age.

4.4 Special warnings for each target species

Treatment of calves with Loxicom 20 minutes before dehorning reduces post-operative pain. Loxicom alone will not provide adequate pain relief during the dehorning procedure. To obtain adequate pain relief during surgery co-medication with an appropriate analgesic is needed.

4.5 Special precautions for use

Special precautions for use in animals

If adverse reactions occur, treatment should be discontinued and the advice of a veterinarian should be sought.
Avoid use in very severely dehydrated, hypovolaemic or hypotensive animals which require parenteral rehydration, as there may be a potential risk of renal toxicity.
In cases of inadequate relief of pain when used in the treatment of equine colic, careful re-evaluation of the diagnosis should be made as this could indicate the need for surgical intervention.

Special precautions to be taken by the person administering the veterinary medicinal product to animals

Accidental self injection may cause pain. People with known hypersensitivity to Non-Steroidal Anti-Inflammatory Drugs (NSAIDs) should avoid contact with the veterinary medicinal product.
In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.

4.6 Adverse reactions (frequency and seriousness)

Administration of the veterinary medicinal product by the subcutaneous route in cattle and the intramuscular route in pigs is well tolerated; only a slight transient swelling at the injection site following subcutaneous administration was observed in less than 10 % of cattle treated in clinical studies.

In horses, a transient swelling at the injection site can occur but resolved without intervention.

In very rare cases anaphylactoid reactions, which may be serious (including fatal), may occur and should be treated symptomatically.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reactions)
- common (more than 1 but less than 10 animals treated in 100 animals)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

4.7 Use during pregnancy, lactation or lay

Cattle and Pigs: Can be used during pregnancy and lactation.
Horses: Do not use in pregnant or lactating mares.

See also section 4.3.

4.8 Interaction with other medicinal products and other forms of interaction

Do not administer concurrently with glucocorticosteroids, other non-steroidal anti-inflammatory drugs or with anti-coagulant agents.

4.9 Amounts to be administered and administration route

Cattle:
Single subcutaneous or intravenous injection at a dosage of 0.5 mg meloxicam/kg body weight (i.e., 2.5 ml/100 kg body weight) in combination with antibiotic therapy or with oral re-hydration therapy, as appropriate. The recommended maximum volume to be administered at a single injection site is 10 ml.

Pigs:
Single intramuscular injection at a dosage of 0.4 mg meloxicam/kg body weight (i.e., 2.0 ml/100 kg body weight) in combination with antibiotic therapy, as appropriate. If required, a second administration of meloxicam can be given after 24 hours. The recommended maximum volume to be administered at a single injection site is 2 ml.

Horses:
Single intravenous injection as a dosage of 0.6 mg meloxicam/kg body weight (i.e., 3.0 ml/100 kg body weight).
For use in the alleviation of inflammation and the relief of pain in both acute and chronic musculoskeletal disorders, a suitable oral therapy containing meloxicam, administered in accordance with label recommendations, may be used for continuation of treatment.
Avoid introduction of contamination during use.

Do not exceed 50 broachings per vial. If more than 50 broachings are required, the use of a draw-off needle is recommended.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

In the case of overdose, symptomatic treatment should be initiated.

4.11 Withdrawal period(s)

Cattle:	Meat and offal:	15 days	Milk:	5 days
Pigs:	Meat and offal:	5 days		
Horses:	Meat and offal:	5 days.		

Not authorised for use in horses producing milk for human consumption.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Anti-inflammatory and antirheumatic products, non-steroids (oxicams)
ATC vet code: QM01AC06

5.1 Pharmacodynamic properties

Meloxicam is a Non-Steroidal Anti-Inflammatory Drug (NSAID) of the oxicam class which acts by inhibition of prostaglandin synthesis, thereby exerting anti-inflammatory, anti-exudative, analgesic and antipyretic effects. It reduces leukocyte infiltration into the inflamed tissue. To a minor extent it also inhibits collagen-induced thrombocyte aggregation. Meloxicam also has anti-endotoxic

properties because it has been shown to inhibit production of thromboxane B_2 induced by *E. coli* endotoxin administration in calves, lactating cows and pigs.

5.2 Pharmacokinetic particulars

Absorption
After a single subcutaneous dose of 0.5 mg meloxicam/kg, C_{max} values of 2.1 µg/ml and 2.7 µg/ml were reached after 7.7 hours and 4 hours in young cattle and lactating cows, respectively.
After two intramuscular doses of 0.4 mg meloxicam/kg, a C_{max} value of 1.9 µg/ml was reached after 1 hour in pigs.

Distribution
More than 98% of meloxicam is bound to plasma proteins. The highest meloxicam concentrations are to be found in liver and kidney. Comparatively low concentrations are detectable in skeletal muscle and fat.

Metabolism
Meloxicam is predominantly found in plasma. In cattle, meloxicam is also a major excretion product in milk and bile whereas urine contains only traces of the parent compound. In pigs, bile and urine contain only traces of the parent compound. Meloxicam is metabolised to an alcohol, an acid derivative and to several polar metabolites. All major metabolites have been shown to be pharmacologically inactive. The metabolism in horses has not been investigated.

Elimination
Meloxicam is eliminated with a half-life of 26 hours and 17.5 hours after subcutaneous injection in young cattle and lactating cows, respectively.

In pigs, after intramuscular administration the mean plasma elimination half-life is approximately 2.5 hours.
In horses, after intravenous injection meloxicam is eliminated with a terminal half-life of 8.5 hours.

Approximately 50% of the administered dose is eliminated via urine and the remainder via faeces.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Ethanol
Meglumine
Glycine
Poloxamer 188
Sodium chloride
Macrogol 300
Hydrochloric acid
Sodium hydroxide
Water for injections

6.2 Major incompatibilities

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years.
Shelf life after first opening the immediate packaging: 28 days.

6.4 Special precautions for storage

This veterinary medicinal product does not require any special storage conditions.

6.5 Nature and composition of immediate packaging

Cardboard box with either 1 or 12 colourless glass injection vial(s) each containing 30 ml, 50 ml or 100 ml. Cardboard box with 1, 6 or 12 colourless glass injection vial(s) each containing 250 ml.
Each vial is closed with a bromobutyl bung and sealed with an aluminium cap.
Not all pack sizes may be marketed.

6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

Norbrook Laboratories (Ireland) Limited
Rossmore Industrial Estate
Monaghan
Ireland

8. MARKETING AUTHORISATION NUMBERS:

EU/2/08/090/010 30 ml
EU/2/08/090/011 50 ml
EU/2/08/090/012 100 ml
EU/2/08/090/013 250 ml
EU/2/08/090/014 6 x 250 ml
EU/2/08/090/015 12 x 30 ml
EU/2/08/090/016 12 x 50 ml
EU/2/08/090/017 12 x 100 ml
EU/2/08/090/018 12 x 250 ml

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 10/02/2009
Date of last renewal: 23/01/2019

10. DATE OF REVISION OF THE TEXT

Detailed information on this veterinary medicinal product is available on the website of the European Medicines Agency http://www.ema.europa.eu/.

PROHIBITION OF SALE, SUPPLY AND/OR USE

Not applicable.

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Loxicom 1 mg chewable tablets for dogs
Loxicom 2.5 mg chewable tablets for dogs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each chewable tablet contains:

Active substance:

Meloxicam 1 mg
Meloxicam 2.5 mg

For the full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Chewable tablet.
Light brown oval biconvex tablet with a score line on one face and plain on the other.
The tablets can be broken into equal halves.

4. CLINICAL PARTICULARS

4.1 Target species

Dogs

4.2 Indications for use, specifying the target species

Alleviation of inflammation and pain in both acute and chronic musculo-skeletal disorders in dogs.

4.3 Contraindications

Do not use in pregnant or lactating animals.
Do not use in animals suffering from gastrointestinal disorders such as irritation and haemorrhage, impaired hepatic, cardiac or renal function and haemorrhagic disorders
Do not use in dogs less than 6 weeks of age or less than 4 kg body weight.
Do not use in case of hypersensitivity to the active substance or to any of the excipients.

4.4 Special warnings for each target species

None

4.5 Special precautions for use

Special precautions for use in animals

If adverse reactions occur, treatment should be discontinued and the advice of a veterinarian should be sought.

Avoid use in any dehydrated, hypovolaemic or hypotensive animal, as there is a potential risk of renal toxicity.
This veterinary medicinal product for dogs should not be used in cats as it is not suitable for use in this species. In cats, a meloxicam containing oral suspension authorised for that species should be used.

Special precautions to be taken by the person administering the veterinary medicinal product to animals

People with known hypersensitivity to non-steroidal anti-inflammatory drugs (NSAIDs) should avoid contact with the veterinary medicinal product.
In case of accidental ingestion, seek medical advice immediately and show the package leaflet or the label to the physician.

4.6 Adverse reactions (frequency and seriousness)

Typical adverse drug reactions of NSAIDs such as loss of appetite, vomiting, diarrhoea, faecal occult blood, apathy and renal failure have occasionally been reported. In very rare cases, haemorrhagic diarrhoea, haematemesis, gastrointestinal ulceration and elevated liver enzymes have been reported. These side effects occur generally within the first treatment week and are in most cases transient and disappear following termination of the treatment but in very rare cases may be serious or fatal.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reactions)
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

4.7 Use during pregnancy, lactation or lay

The safety of the veterinary medicinal product has not been established during pregnancy and lactation (see section 4.3).

4.8 Interaction with other medicinal products and other forms of interaction

Other NSAIDs, diuretics, anticoagulants, aminoglycoside antibiotics and substances with high protein binding may compete for binding and thus lead to toxic effects. This veterinary medicinal product must not be administered in conjunction with other NSAIDs or glucocorticosteroids.
Pre-treatment with anti-inflammatory substances may result in additional or increased adverse effects and accordingly a treatment-free period with such drugs should be observed for at least 24 hours before commencement of treatment. The treatment-free period, however, should take into account the pharmacological properties of the veterinary medicinal products used previously.

4.9 Amounts to be administered and administration route

Oral use.

Initial treatment is a single dose of 0.2 mg meloxicam/kg body weight on the first day, which can be given orally or alternatively using meloxicam 5 mg/ml solution for injection for dogs and cats.

Treatment is to be continued once daily by oral administration (at 24-hour intervals) at a maintenance dose of 0.1 mg meloxicam/kg body weight.

Each chewable tablet contains 1 mg or 2.5 mg meloxicam, which corresponds to the daily maintenance dose for a 10 kg body weight dog, or a 25 kg body weight dog, respectively.
Each chewable tablet can be halved for accurate dosing according to the individual body weight of the dog. The tablets can be administered with or without food, are flavoured and are taken by most dogs voluntarily.

Dose scheme for the maintenance dose:

Body weight (kg)	Number of chewable tablets 1 mg	Number of chewable tablets 2.5 mg	mg/kg
4.0-7.0	½		0.13-0.1
7.1-10.0	1		0.14-0.1
10.1-15.0	1½		0.15-0.1
15.1-20.0	2		0.13-0.1
20.1-25.0		1	0.12-0.1
25.1-35.0		1½	0.15-0.1
35.1-50.0		2	0.14-0.1

The use of a meloxicam containing oral suspension for dogs may be considered for an even more precise dosing. For dogs weighing less than 4 kg the use of meloxicam containing oral suspension for dogs is recommended.
A clinical response is normally seen within 3-4 days. Treatment should be discontinued after 10 days if no clinical improvement is apparent.
To ensure correct dosage, bodyweight should be determined as accurately as possible to avoid underdosing or overdosing.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

In case of overdose, symptomatic treatment should be initiated.

4.11 Withdrawal period(s)

Not applicable.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Anti-inflammatory and anti-rheumatic products, non-steroids (oxicams), ATC vet code: QM01AC06

5.1 Pharmacodynamic properties

Meloxicam is a non-steroidal anti-inflammatory drug (NSAID) of the oxicam class which acts by inhibition of prostaglandin synthesis, thereby exerting anti-inflammatory, analgesic, anti-exudative and antipyretic effects. It reduces leukocyte infiltration into the inflamed tissue. To a minor extent it also inhibits collagen-induced thrombocyte aggregation. *In vitro* and *in vivo* studies demonstrated that meloxicam inhibits cyclooxygenase-2 (COX-2) to a greater extent than cyclooxygenase-1 (COX-1).

5.2 Pharmacokinetic properties

Absorption

Meloxicam is completely absorbed following oral administration and maximal plasma concentrations are obtained after approximately 7.5 hours. When the veterinary medicinal product is used according

to the recommended dosage regime, steady state concentrations of meloxicam in plasma are reached on the second day of treatment.

Distribution

There is a linear relationship between the dose administered and plasma concentration observed in the therapeutic dose range. Approximately 97% of meloxicam is bound to plasma proteins. The volume of distribution is 0.3 l/kg.

Metabolism

Meloxicam is predominantly found in plasma and is also a major biliary excretion product whereas urine contains only traces of the parent compound. Meloxicam is metabolised to an alcohol, an acid derivative and to several polar metabolites. All major metabolites have been shown to be pharmacologically inactive.

Elimination

Meloxicam is eliminated with a half-life of 24 hours. Approximately 75% of the administered dose is eliminated via faeces and the remainder via urine.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

-Sodium starch glycolate, type A
-Spray dried pork liver
-Lactose monohydrate
-Povidone K30
-Sucrose
-Microcrystalline cellulose and guar gum
-Microcrystalline cellulose
-Wheatgerm defatted flour
-Yeast extract (dried)
-Magnesium stearate

6.2 Major incompatibilities

None known.

6.3 Shelf life

Shelf-life of the veterinary medicinal product as packaged for sale: 18 months.
Any unused half tablets may be returned to open blister and stored for up to 24 hours.

6.4 Special precautions for storage

Do not store above 25°C.
Store in the original package in order to protect from light.

6.5 Nature and composition of immediate packaging

Blister packs of 10 tablets per strip composed of PVC/PVDC base foil and aluminium lidding foil in cartons containing 10, 20, 100 or 500 tablets.

Not all pack sizes may be marketed.

6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

Norbrook Laboratories (Ireland) Limited
Rossmore Industrial Estate
Monaghan
Ireland

8. MARKETING AUTHORISATION NUMBER(S)

Loxicom 1 mg chewable tablets for dogs:
EU/2/08/090/019 – 1 x 10 tabletes
EU/2/08/090/020 – 2 x 10 tabletes
EU/2/08/090/021 – 10 x 10 tabletes
EU/2/08/090/022 – 50 x 10 tabletes

Loxicom 2.5 mg chewable tablets for dogs:
EU/2/08/090/023 – 1 x 10 tablets
EU/2/08/090/024 – 2 x 10 tablets
EU/2/08/090/025 – 10 x 10 tablets
EU/2/08/090/026 – 50 x 10 tablets

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 10/02/2009
Date of last renewal: 23/01/2019

10. DATE OF REVISION OF THE TEXT

Detailed information on this veterinary medicinal product is available on the website of the European Medicines Agency http://www.ema.europa.eu/.

PROHIBITION OF SALE, SUPPLY AND/OR USE

Not applicable.

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Loxicom 50 mg/g oral paste for horses

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

One gram contains:

Active substance:

Meloxicam 50 mg

Excipient:

Benzyl alcohol 10 mg

For the full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Oral paste.
A pale yellow homogenous paste.

4. CLINICAL PARTICULARS

4.1 Target species

Horses.

4.2 Indications for use, specifying the target species

Alleviation of inflammation and relief of pain in both acute and chronic musculo-skeletal disorders in horses.

4.3 Contraindications

Do not use in pregnant or lactating mares.
Do not use in horses suffering from gastrointestinal disorders such as irritation and haemorrhage, impaired hepatic, cardiac or renal function and haemorrhagic disorders.
Do not use in case of hypersensitivity to the active substance or to any of the excipients.
Do not use in horses less than 6 weeks of age.

4.4 Special warnings for each target species

None

4.5 Special precautions for use

Special precautions for use in animals

Avoid use in any dehydrated, hypovolaemic or hypotensive animals as there is a potential risk of renal toxicity.
Do not exceed the recommended dose or duration of treatment due to the possibility of severe adverse reactions. See section 4.10.

Special precautions to be taken by the person administering the veterinary medicinal product to animals

People with known hypersensitivity to Non-Steroidal Anti-Inflammatory Drugs (NSAIDs) should avoid contact with the veterinary medicinal product.
Avoid skin and eye contact with the product. If skin and/or eye contact occurs, wash the affected parts immediately with water. Should irritation occur and persist, seek medical advice.
In case of accidental ingestion, seek medical advice immediately and show the package leaflet or the label to the physician.

4.6 Adverse reactions (frequency and seriousness)

Isolated cases of adverse reactions typically associated with NSAIDs were observed in clinical trials (slight urticaria, diarrhoea). Symptoms were reversible. Commonly, a reduction in blood albumin concentration will occur during the period of treatment (up to 14 days).
In very rare cases loss of appetite, lethargy, abdominal pain and colitis have been reported. In very rare cases anaphylactoid reactions, which may be serious (including fatal), may occur and should be treated symptomatically. If adverse reactions occur, treatment should be discontinued and the advice of a veterinarian should be sought.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

4.7 Use during pregnancy, lactation or lay

Laboratory studies in cattle have not provided any evidence for teratogenic, foetotoxic, or maternotoxic effects. However, no data have been generated in horses. Therefore the use in this species is not recommended during pregnancy and lactation.

4.8 Interaction with other medicinal products and other forms of interaction

Do not administer concurrently with glucocorticosteroids, other non-steroidal anti-inflammatory veterinary medicinal products or with anticoagulant agents.

4.9 Amounts to be administered and administration route

Administer 0.6 mg/kg body weight, once daily for up to 14 days.
To be administered directly into the mouth over the back of the tongue keeping the animal's head raised until swallowed.

One syringe division of paste should be administered per 50 kg bodyweight. The syringe has an integrated adapter and has a kg/bodyweight graduation. Each syringe delivers 420 mg meloxicam, sufficient to treat 700 kg of bodyweight.

Avoid introduction of contamination during use.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

The following clinical signs (some of which may be serious) have been reported in clinical studies following administration of the product at 5x overdose: dull behaviour, diarrhoea, oedema, buccal mucosal ulceration and/or dark coloured urine.
In case of overdose, symptomatic treatment should be initiated.

4.11 Withdrawal period(s)

Meat and offal: 3 days.
Not authorised for use in animals producing milk for human consumption.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Anti-inflammatory and antirheumatic products, non-steroids (oxicams)
ATC vet code: QM01AC06

5.1 Pharmacodynamic properties

Meloxicam is a Non-Steroidal Anti-Inflammatory Drug (NSAID) of the oxicam class which acts by inhibition of prostaglandin synthesis, thereby exerting anti-inflammatory, analgesic, anti-exudative and antipyretic effects. It reduces leukocyte infiltration into the inflamed tissue. To a minor extent it also inhibits collagen-induced thrombocyte aggregation. Meloxicam also has anti-endotoxic properties because it has been shown to inhibit production of thromboxane B_2 induced by intravenous *E. coli* endotoxin administration in calves and pigs.

5.2 Pharmacokinetic particulars

Absorption
When the product is used according to the recommended dosage regime the oral bioavailability is approximately 98%. Maximal plasma concentrations are obtained after approximately 2 - 3 hours. The accumulation factor of 1.08 suggests that meloxicam does not accumulate when administered daily.

Distribution
Approximately 98% of meloxicam is bound to plasma proteins. The volume of distribution is 0.12 l/kg.

Metabolism
The metabolism is qualitatively similar in rats, mini-pigs, humans, cattle and pigs although quantitatively there are differences. The major metabolites found in all species were the 5-hydroxy- and 5-carboxy-metabolites and the oxalyl-metabolite. The metabolism in horses was not investigated. All major metabolites have been shown to be pharmacologically inactive.

Elimination
Meloxicam is eliminated with a terminal half-life of 7.7 hours.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Hydroxypropyl cellulose
Glycerol
Xanthan gum

Apple flavour
Sorbitol
Benzyl alcohol
Saccharin sodium powder
Purified water

6.2 Major incompatibilities

None known.

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sales: 18 months.
Shelf life after first opening the immediate packaging: 28 days

6.4 Special precautions for storage

Store below 30 ºC

6.5 Nature and composition of immediate packaging

Low-density polyethylene pre-filled syringes containing 8.4 g of product in cartons of 1, 7, or 14 syringes. Each syringe has an integrated adapter with a "kg/body weight" graduation, in divisions of paste per 50 kg bodyweight.

Not all pack sizes may be marketed.

6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

Norbrook Laboratories (Ireland) Limited
Rossmore Industrial Estate
Monaghan
Ireland

8. MARKETING AUTHORISATION NUMBERS:

EU/2/08/090/029 (1 syringe)
EU/2/08/090/030 (1 x 7 syringes)
EU/2/08/090/031 (1 x 14 syringes)

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 10/02/2009
Date of last renewal: 23/01/2019

10. DATE OF REVISION OF THE TEXT

Detailed information on this veterinary medicinal product is available on the website of the European Medicines Agency http://www.ema.europa.eu/.

PROHIBITION OF SALE, SUPPLY AND/OR USE

Not applicable.

ANNEX II

A. MANUFACTURER RESPONSIBLE FOR BATCH RELEASE

B. CONDITIONS OR RESTRICTIONS OF THE MARKETING AUTHORISATION REGARDING SUPPLY OR USE

C. STATEMENT OF THE MRLs

Loxicom 0.5 mg/ml oral suspension for dogs

A. MANUFACTURER RESPONSIBLE FOR BATCH RELEASE

Name and address of the manufacturer responsible for batch release

Norbrook Manufacturing Limited
Rossmore Industrial Estate
Monaghan Town
Co. Monaghan
H18 W620
Ireland

Norbrook Laboratories Limited
105 Armagh Road
Newry
Co. Down, BT35 6PU
United Kingdom

B. CONDITIONS OR RESTRICTIONS OF THE MARKETING AUTHORISATION REGARDING SUPPLY OR USE

To be supplied only on veterinary prescription.

C. STATEMENT OF MRLs

Not applicable.

Loxicom 1.5 mg/ml oral suspension for dogs

A. MANUFACTURER RESPONSIBLE FOR BATCH RELEASE

Name and address of the manufacturer responsible for batch release

Norbrook Manufacturing Limited
Rossmore Industrial Estate
Monaghan Town
Co. Monaghan
H18 W620
Ireland

Norbrook Laboratories Limited
105 Armagh Road
Newry
Co. Down, BT35 6PU
United Kingdom

B. CONDITIONS OR RESTRICTIONS OF THE MARKETING AUTHORISATION REGARDING SUPPLY OR USE

Veterinary medicinal product subject to prescription

C. STATEMENT OF MRLs

Not applicable.

Loxicom 5 mg/ml solution for injection for dogs and cats

A. MANUFACTURER RESPONSIBLE FOR BATCH RELEASE

Name and address of the manufacturer responsible for batch release

Norbrook Manufacturing Limited
Rossmore Industrial Estate
Monaghan Town
Co. Monaghan
H18 W620
Ireland

Norbrook Laboratories Limited
105 Armagh Road
Newry
Co. Down, BT35 6PU
United Kingdom

B. CONDITIONS OR RESTRICTIONS OF THE MARKETING AUTHORISATION REGARDING SUPPLY OR USE

Veterinary medicinal product subject to prescription

C. STATEMENT OF MRLs

Not applicable.

Loxicom 0.5 mg/ml oral suspension for cats

A. MANUFACTURER RESPONSIBLE FOR BATCH RELEASE

Name and address of the manufacturer responsible for batch release

Norbrook Manufacturing Limited
Rossmore Industrial Estate
Monaghan Town
Co. Monaghan
H18 W620
Ireland

Norbrook Laboratories Limited
105 Armagh Road
Newry
Co. Down, BT35 6PU
United Kingdom

B. CONDITIONS OR RESTRICTIONS OF THE MARKETING AUTHORISATION REGARDING SUPPLY OR USE

Veterinary medicinal product subject to prescription

C. STATEMENT OF MRLs

Not applicable.

Loxicom 20 mg/ml solution for injection for cattle, pigs and horses.

A. MANUFACTURER RESPONSIBLE FOR BATCH RELEASE

Name and address of the manufacturer responsible for batch release

Norbrook Manufacturing Limited
Rossmore Industrial Estate
Monaghan Town
Co. Monaghan
H18 W620
Ireland

Norbrook Laboratories Limited
105 Armagh Road
Newry
Co. Down, BT35 6PU
United Kingdom

B. CONDITIONS OR RESTRICTIONS OF THE MARKETING AUTHORISATION REGARDING SUPPLY OR USE

Veterinary medicinal product subject to prescription

C. STATEMENT OF MRLs

The active substance in Loxicom 20 mg/ml solution for injection for cattle, pigs and horses is an allowed substance as described in table 1 of the annex to Commission Regulation (EU) No 37/2010:

Pharmacologically active substance	Marker residue	Animal species	MRL	Target tissues	Other provisions	Therapeutic classification
Meloxicam	Meloxicam	Bovine, caprine, porcine, rabbit, *Equidae*	20 µg/kg 65 µg/kg 65 µg/kg	Muscle Liver Kidney	NO ENTRY	Anti-inflammatory agents/ Nonsteroidal anti-inflammatory agents
		Bovine, caprine	15 µg/kg	Milk		

The excipients listed in section 6.1 of the SPC are either allowed substances for which table 1 of the annex to Commission Regulation (EU) No 37/2010 indicates that no MRLs are required or are considered as not falling within the scope of Regulation (EC) No 470/2009 when used as in this product.

Loxicom 1 mg chewable tablets for dogs
Loxicom 2.5 mg chewable tablets for dogs

A. MANUFACTURER RESPONSIBLE FOR BATCH RELEASE

Name and address of the manufacturer responsible for batch release

Norbrook Manufacturing Limited
Rossmore Industrial Estate
Monaghan Town
Co. Monaghan
H18 W620
Ireland

Norbrook Laboratories Limited
105 Armagh Road
Newry
Co. Down, BT35 6PU
United Kingdom

B. CONDITIONS OR RESTRICTIONS OF THE MARKETING AUTHORISATION REGARDING SUPPLY OR USE

Veterinary medicinal product subject to prescription

C. STATEMENT OF MRLs

Not applicable.

Loxicom 50 mg/g oral paste for horses

A. MANUFACTURER RESPONSIBLE FOR BATCH RELEASE

Name and address of the manufacturer responsible for batch release

Norbrook Manufacturing Limited
Rossmore Industrial Estate
Monaghan Town
Co. Monaghan
H18 W620
Ireland

Norbrook Laboratories Limited
105 Armagh Road
Newry
Co. Down, BT35 6PU
United Kingdom

B. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE

Veterinary medicinal product subject to prescription

C. STATEMENT OF THE MRLs

The active substance in Loxicom is an allowed substance as described in table 1 of the annex to Commission Regulation (EU) No 37/2010.

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions	Therapeutic classification
Meloxicam	Meloxicam	Bovine, caprine, porcine, rabbit, *Equidae*	20 µg/kg 65 µg/kg 65 µg/kg	Muscle Liver Kidney	No entry	Anti-inflammatory agents/Non-steroidal anti-inflammatory agents
		Bovine, caprine	15 µg/kg	Milk		

The excipients listed in section 6.1 of the SPC are either allowed substances for which table 1 of annex to Commission Regulation (EU) No 37/2010 indicates that no MRLs are required or are considered as not falling within the scope of Regulation (EC) No 470/2009 when used as in this product.

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Carton box 15 and 30 ml bottle

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Loxicom 0.5 mg/ml oral suspension for dogs
meloxicam

2. STATEMENT OF THE ACTIVE SUBSTANCES

Each ml contains:

Meloxicam 0.5 mg
Sodium benzoate 1.5 mg

3. PHARMACEUTICAL FORM

Oral suspension.

4. PACKAGE SIZE

15 ml, 30 ml

5. TARGET SPECIES

Dogs.

6. INDICATION(S)

Alleviation of inflammation and pain in both acute and chronic musculo-skeletal disorders.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Shake well before use.
To be administered with food or directly into the mouth.
Avoid introduction of contamination during use.
Oral use.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

9. SPECIAL WARNING(S), IF NECESSARY

Do not use in pregnant or lactating animals.

10. EXPIRY DATE

EXP:
Once opened use within 6 months.

11. SPECIAL STORAGE CONDITIONS

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS,IF ANY

Disposal: read package leaflet before use.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

For animal treatment only. To be supplied only on veterinary prescription.

14. THE WORDS "KEEP OUR OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Norbrook Laboratories (Ireland) Limited
Rossmore Industrial Estate
Monaghan
Ireland

16. MARKETING AUTHORISATION NUMBER(S)

EU/2/08/090/001 [15 ml]
EU/2/08/090/002 [30 ml]

17. MANUFACTURERS BATCH NUMBER

BN:

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

15 and 30 ml bottle

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Loxicom 0.5 mg/ml oral suspension for dogs
meloxicam

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Meloxicam 0.5 mg/ml

3. CONTENT BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

15 ml
30 ml

4. ROUTE OF ADMINISTRATION

Oral use.
Shake well before use.

5. WITHDRAWAL PERIOD(S)

6. BATCH NUMBER

BN:

7. EXPIRY DATE

EXP:
Once opened, use within 6 months

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Carton box 10, 32, 100, 2 x 100 ml and 200 ml bottle

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Loxicom 1.5 mg/ml oral suspension for dogs.
meloxicam

2. STATEMENT OF THE ACTIVE SUBSTANCE(S)

Each ml contains:

Meloxicam	1.5 mg
Sodium benzoate	1.5 mg

3. PHARMACEUTICAL FORM

Oral Suspension.

4. PACKAGE SIZES

10 ml
32 ml
100 ml
200 ml
2 x 100 ml

5. TARGET SPECIES

Dogs.

6. INDICATIONS

Alleviation of inflammation and pain in both acute and chronic musculo-skeletal disorders in dogs.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Shake well before use.
To be administered with food or directly into the mouth.
Avoid introduction of contamination during use.
Oral use.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

9. SPECIAL WARNING(S), IF NECESSARY

Do not use in pregnant or lactating animals.

10. EXPIRY DATE

EXP:
Once opened use within 6 months.

11 SPECIAL STORAGE CONDITIONS

12 SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: read package leaflet before use.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

For animal treatment only. To be supplied only on veterinary prescription.

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Norbrook Laboratories (Ireland) Limited
Rossmore Industrial Estate
Monaghan
Ireland

16. MARKETING AUTHORISATION NUMBER(S)

EU/2/08/090/003 [10 ml]
EU/2/08/090/004 [32 ml]
EU/2/08/090/005 [100 ml]
EU/2/08/090/032 [200 ml]
EU/2/08/090/033 [2 x 100 ml]

17. MANUFACTURER'S BATCH NUMBER

BN:

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

100 ml, 2 x 100 ml and 200 ml bottle

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Loxicom 1.5 mg/ml oral suspension for dogs.
meloxicam

2. STATEMENT OF THE ACTIVE SUBSTANCE(S)

Each ml contains:

Meloxicam	1.5 mg
Sodium benzoate	1.5 mg

3. PHARMACEUTICAL FORM

Oral Suspension.

4. PACKAGE SIZES

100 ml.
200 ml

5. TARGET SPECIES

Dogs.

6. INDICATIONS

Alleviation of inflammation and pain in both acute and chronic musculo-skeletal disorders in dogs.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Oral use.
Shake well before use.
To be administered with food or directly into the mouth.
Avoid introduction of contamination during use.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

9. SPECIAL WARNING(S), IF NECESSARY

Do not use in pregnant or lactating animals.

10. EXPIRY DATE

EXP:
Once opened use within 6 months.

11 SPECIAL STORAGE CONDITIONS

12 SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: read package leaflet before use.
Dispose of waste material in accordance with local requirements.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

For animal treatment only. To be supplied only on veterinary prescription.

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Norbrook Laboratories (Ireland) Limited
Rossmore Industrial Estate
Monaghan
Ireland

16. MARKETING AUTHORISATION NUMBER(S)

EU/2/08/090/005 [100 ml]
EU/2/08/090/032 [200 ml]
EU/2/08/090/033 [2 x 100 ml]

17. MANUFACTURER'S BATCH NUMBER

BN:

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

10 and 32 ml bottle

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Loxicom 1.5 mg/ml oral suspension for dogs.
meloxicam

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Meloxicam 1.5 mg/ml

3. CONTENT BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

10 ml
32 ml

4. ROUTE(S) OF ADMINISTRATION

Oral use.

Read the package leaflet before use.

5. WITHDRAWAL PERIOD(S)

6. BATCH NUMBER

BN:

7. EXPIRY DATE

EXP:
Once opened, use within 6 months.

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Carton box 10 ml, 20 ml and 100 ml bottle

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Loxicom 5 mg/ml solution for injection for dogs and cats
meloxicam

2. STATEMENT OF THE ACTIVE SUBSTANCE(S)

Each ml contains:
Meloxicam 5 mg
Ethanol, anhydrous 150 mg

3. PHARMACEUTICAL FORM

Solution for injection.

4. PACKAGE SIZES

10 ml
20 ml.
100 ml

5. TARGET SPECIES

Dogs and cats.

6. INDICATIONS

Dogs:
Alleviation of inflammation and pain in both acute and chronic musculo-skeletal disorders.
Reduction of post-operative pain and inflammation following orthopaedic and soft tissue surgery.

Cats:
Reduction of post-operative pain after ovariohysterectomy and minor soft tissue surgery.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Dogs:
Musculo-skeletal disorders: single subcutaneous injection.
Post-operative pain: single intravenous or subcutaneous injection.

Cats:
Post-operative pain: single subcutaneous injection.

Avoid introduction of contamination during use.

Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

9. SPECIAL WARNING(S), IF NECESSARY

Do not use in pregnant or lactating animals.

10. EXPIRY DATE

EXP:
Shelf-life of broached vial: 28 days.

11. SPECIAL STORAGE CONDITIONS

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: read package leaflet before use.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

For animal treatment only. To be supplied only on veterinary prescription.

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Norbrook Laboratories (Ireland) Limited
Rossmore Industrial Estate
Monaghan
Ireland

16. MARKETING AUTHORISATION NUMBER(S)

EU/2/08/090/006 [10 ml]
EU/2/08/090/007 [20 ml]
EU/2/08/090/008 [100 ml]

17. MANUFACTURER'S BATCH NUMBER

BN:

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

100 ml bottle

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Loxicom 5 mg/ml solution for injection for dogs and cats
meloxicam

2. STATEMENT OF THE ACTIVE SUBSTANCE(S)

Each ml contains:

Meloxicam	5 mg
Ethanol, anhydrous	150 mg

3. PHARMACEUTICAL FORM

Solution for injection.

4. PACKAGE SIZES

100 ml

5. TARGET SPECIES

Dogs and cats.

6. INDICATIONS

Dogs:
Alleviation of inflammation and pain in both acute and chronic musculo-skeletal disorders. Reduction of post-operative pain and inflammation following orthopaedic and soft tissue surgery.

Cats:
Reduction of post-operative pain after ovariohysterectomy and minor soft tissue surgery.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Dogs:
Musculo-skeletal disorders: single subcutaneous injection.
Post-operative pain: single intravenous or subcutaneous injection.

Cats:
Post-operative pain: single subcutaneous injection.

Avoid introduction of contamination during use.

Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

9. SPECIAL WARNING(S), IF NECESSARY

Do not use in pregnant or lactating animals.

10. EXPIRY DATE

EXP:
Shelf-life of broached vial: 28 days.

11. SPECIAL STORAGE CONDITIONS

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: read package leaflet before use.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

For animal treatment only. To be supplied only on veterinary prescription.

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Norbrook Laboratories (Ireland) Limited
Rossmore Industrial Estate
Monaghan
Ireland

16. MARKETING AUTHORISATION NUMBER(S)

EU/2/08/090/008 [100 ml]

17. MANUFACTURER'S BATCH NUMBER

BN:

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

10 and 20 ml bottle

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Loxicom 5 mg/ml solution for injection for dogs and cats
meloxicam

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Meloxicam 5 mg/ml

3. CONTENT BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

10 ml
20 ml

4. ROUTE(S) OF ADMINISTRATION

Dogs: intravenous or subcutaneous use.
Cats: subcutaneous use.

5. WITHDRAWAL PERIOD(S)

6. BATCH NUMBER

BN:

7. EXPIRY DATE

EXP:
Shelf-life of opened bottle: 28 days

Once broached, use by…….

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Carton box 5 ml, 15 ml and 30 ml bottle

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Loxicom 0.5 mg/ml oral suspension for cats
meloxicam

2. STATEMENT OF ACTIVE SUBSTANCES

Meloxicam: 0.5 mg/ml
Sodium benzoate: 1.5 mg/ml

3. PHARMACEUTICAL FORM

Oral suspension.

4. PACKAGE SIZE

5 ml, 15 ml and 30 ml

5. TARGET SPECIES

Cats.

6. INDICATION(S)

Alleviation of mild to moderate post-operative pain and inflammation following surgical procedures in cats, e.g. orthopaedic and soft tissue surgery.
Alleviation of inflammation and pain in acute and chronic musculo-skeletal disorders.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Shake well before use.
To be administered orally either mixed with food or directly into the mouth using the measuring syringe provided.
Avoid introduction of contamination during use.
Oral use.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

9. SPECIAL WARNING(S), IF NECESSARY

Do not use in pregnant or lactating animals.
Do not use in cats suffering from gastrointestinal disorders such as irritation and haemorrhage, impaired hepatic, cardiac or renal function and haemorrhagic disorders.
Do not use in case of hypersensitivity to the active substance or to any of the excipients.
Do not use in cats less than 6 weeks old.

10. EXPIRY DATE

EXP:
Shelf-life of opened bottle: 6 months.

11. SPECIAL STORAGE CONDITIONS

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: read package leaflet before use.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

For animal treatment only. To be supplied only on veterinary prescription.

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Norbrook Laboratories (Ireland) Limited
Rossmore Industrial Estate
Monaghan
Ireland

16. MARKETING AUTHORISATION NUMBER(S)

EU/2/08/090/027 (5ml)
EU/2/08/090/009 (15ml)
EU/2/08/090/028 (30ml)

17. MANUFACTURER'S BATCH NUMBER

BN:

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

5 ml, 15 ml and 30 ml bottle label

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Loxicom 0.5 mg/ml oral suspension for cats.
meloxicam

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Meloxicam 0.5 mg/ml

3. CONTENT BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

5 ml, 15 ml and 30 ml

4. ROUTE(S) OF ADMINISTRATION

Oral use.
Read the package leaflet before use.

5. WITHDRAWAL PERIOD(S)

6. BATCH NUMBER

BN:

7. EXPIRY DATE

EXP:
Shelf-life of opened bottle: 6 months.
Once broached, use by……..

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Carton box 30 ml, 50 ml , 100 ml and 250 ml bottle

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Loxicom 20 mg/ml solution for injection for cattle, pigs and horses
meloxicam

2. STATEMENT OF THE ACTIVE SUBSTANCE(S)

Meloxicam 20 mg/ml
Ethanol 150 mg/ml

3. PHARMACEUTICAL FORM

Solution for injection.

4. PACKAGE SIZES

1 x 30 ml
1 x 50 ml
1 x 100 ml
1 x 250 ml
6 x 250 ml
12 x 30 ml
12 x 50 ml
12 x 100 ml
12 x 250 ml

5. TARGET SPECIES

Cattle, pigs and horses

6. INDICATIONS

Cattle:
Acute respiratory infection.
Diarrhoea in calves of over one week of age and young, non-lactating cattle.
Acute mastitis.
Relief of post-operative pain following dehorning in calves.

Pigs:
Non-infectious locomotor disorders.
Puerperal septicaemia and toxaemia (MMA syndrome) with antibiotic therapy.

Horses:
Acute and chronic musculo-skeletal disorders.

Pain associated with equine colic.

7. METHOD AND ROUTES OF ADMINISTRATION

Cattle: Single subcutaneous or intravenous injection.
Pigs: Single intramuscular injection. If required, a second administration can be given after 24 hours.
Horses: Single intravenous injection.

Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

Cattle: Meat and offal: 15 days Milk: 5 days
Pigs: Meat and offal: 5 days
Horses: Meat and offal: 5 days.
Not authorised for use in horses producing milk for human consumption.

9. SPECIAL WARNING(S), IF NECESSARY

10. EXPIRY DATE

EXP {month/year}
Shelf life of broached vial: 28 days.
Once broached, use by …

11. SPECIAL STORAGE PRECAUTIONS

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS WASTE MATERIALS, IF ANY

Disposal: read package leaflet.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE , if applicable

For animal treatment only. To be supplied on veterinary prescription.

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Norbrook Laboratories (Ireland) Limited
Rossmore Industrial Estate
Monaghan
Ireland

16. MARKETING AUTHORISATION NUMBERS

EU/2/08/090/010 30 ml
EU/2/08/090/011 50 ml
EU/2/08/090/012 100 ml
EU/2/08/090/013 250 ml
EU/2/08/090/014 6 x 250 ml
EU/2/08/090/015 12 x 30 ml
EU/2/08/090/016 12 x 50 ml
EU/2/08/090/017 12 x 100 ml
EU/2/08/090/018 12 x 250 ml

17. MANUFACTURER'S BATCH NUMBER

BN:

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

100 ml and 250 ml bottle

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Loxicom 20 mg/ml solution for Injection for cattle, pigs and horses
meloxicam

2. STATEMENT OF THE ACTIVE SUBSTANCE(S)

Meloxicam 20 mg/ml
Ethanol 150 mg/ml

3. PHARMACEUTICAL FORM

Solution for injection.

4. PACKAGE SIZES

100 ml
250 ml

5. TARGET SPECIES

Cattle, pigs and horses

6. INDICATION(S)

Cattle:
Acute respiratory infection.
Diarrhoea in calves of over one week of age and young, non-lactating cattle.
Acute mastitis.
Relief of post-operative pain following dehorning in calves.

Pigs:
Non-infectious locomotor disorders.
Puerperal septicaemia and toxaemia (MMA syndrome) with antibiotic therapy.

Horses:
Acute and chronic musculo-skeletal disorders.
Pain associated with equine colic.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Cattle: Single SC or IV injection.
Pigs: Single IM injection. If required, a second administration can be given after 24 hours.

Horses: Single IV injection.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

Cattle: Meat and offal: 15 days Milk: 5 days
Pigs: Meat and offal: 5 days
Horses: Meat and offal: 5 days.
Not authorised for use in horses producing milk for human consumption.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}
Once broached, use by …

11. SPECIAL STORAGE PRECAUTIONS

Read the package leaflet before use.

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Dispose of in accordance with local requirements.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE , if applicable

For animal treatment only. To be supplied only on veterinary prescription.

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Norbrook Laboratories (Ireland) Limited
Rossmore Industrial Estate
Monaghan
Ireland

16. MARKETING AUTHORISATION NUMBERS

EU/2/08/090/012 100 ml
EU/2/08/090/013 250 ml
EU/2/08/090/014 6 x 250 ml
EU/2/08/090/017 12 x 100 ml
EU/2/08/090/018 12 x 250 ml

17. MANUFACTURER'S BATCH NUMBER

BN:

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

30 ml and 50 ml bottle

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Loxicom 20 mg/ml solution for injection for cattle, pigs and horses
meloxicam

2. QUANTITY OF THE ACTIVE SUBSTANCE

Meloxicam 20 mg/ml

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER

30 ml
50 ml

4. ROUTES OF ADMINISTRATION

Cattle: SC or IV
Pigs: IM
Horses: IV

5. WITHDRAWAL PERIOD(S)

Cattle: Meat and offal: 15 days Milk: 5 days
Pigs: Meat and offal: 5 days
Horses: Meat and offal: 5 days.
Not authorised for use in horses producing milk for human consumption.

6. BATCH NUMBER

BN {number}

7. EXPIRY DATE

EXP {month/year}
Shelf life of broached vial: 28 Days
Once broached, use by …

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Carton

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Loxicom 1 mg chewable tablets for dogs
Loxicom 2.5 mg chewable tablets for dogs
meloxicam

2. STATEMENT OF ACTIVE SUBSTANCES

Meloxicam 1 mg / chewable tablet
Meloxicam 2.5 mg / chewable tablet

3. PHARMACEUTICAL FORM

Chewable tablet

4. PACKAGE SIZE

10 tablets
20 tablets
100 tablets
500 tablets

5. TARGET SPECIES

Dogs

6. INDICATION(S)

Alleviation of inflammation and pain in both acute and chronic musculo-skeletal disorders in dogs.

7. METHOD AND ROUTE OF ADMINISTRATION

To ensure correct dosage, bodyweight should be determined as accurately as possible to avoid underdosing or overdosing.
Read the package leaflet before use.
Oral use.

8. WITHDRAWAL PERIOD(S)

9. SPECIAL WARNING(S), IF NECESSARY

10. EXPIRY DATE

EXP {month/year}
Shelf-life of the halved tablet: 24-hours

11. SPECIAL STORAGE CONDITIONS

Do not store above 25°C.
Store in the original package in order to protect from light.

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: read package leaflet before use.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

For animal treatment only. To be supplied only on veterinary prescription.

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Norbrook Laboratories (Ireland) Limited
Rossmore Industrial Estate
Monaghan
Ireland

16. MARKETING AUTHORISATION NUMBER(S)

Loxicom 1 mg chewable tablets for dogs:
EU/2/08/090/019 – 1 x 10 tablets
EU/2/08/090/020 – 2 x 10 tablets
EU/2/08/090/021 – 10 x 10 tablets
EU/2/08/090/022 – 50 x 10 tablets

Loxicom 2.5 mg chewable tablets for dogs:
EU/2/08/090/023 – 1 x 10 tablets
EU/2/08/090/024 – 2 x 10 tablets
EU/2/08/090/025 – 10 x 10 tablets
EU/2/08/090/026 – 50 x 10 tablets

17. MANUFACTURER'S BATCH NUMBER

BN

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

Blisters

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Loxicom 1 mg chewable tablets for dogs
Loxicom 2.5 mg chewable tablets for dogs
meloxicam

2. NAME OF THE MARKETING AUTHORISATION HOLDER

Norbrook Laboratories Limited

3. EXPIRY DATE

EXP

4. BATCH NUMBER

BN

5. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Carton Box labelling

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Loxicom 50 mg/g oral paste for horses
meloxicam

2. STATEMENT OF THE ACTIVE SUBSTANCES

Meloxicam 50 mg/g
Benzyl alcohol 10 mg/g

3. PHARMACEUTICAL FORM

Oral paste

4. PACKAGE SIZES

1 syringe
7 syringes
14 syringes

5. TARGET SPECIES

Horses

6. INDICATION(S)

Alleviation of inflammation and relief of pain in both acute and chronic musculo-skeletal disorders in horses

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Oral use
Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

Horses: Meat and offal: 3 days.
Not authorised for use in animals producing milk for human consumption.

9. SPECIAL WARNING(S), IF NECESSARY

10. EXPIRY DATE

EXP {month/year}
Shelf life after first opening the immediate packaging: 28 days

11. SPECIAL STORAGE CONDITIONS

Store below 30 ºC.

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS WASTE MATERIALS, IF ANY

Disposal: read package leaflet before use.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE , if applicable

For animal treatment only. To be supplied only on veterinary prescription.

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Norbrook Laboratories (Ireland) Limited
Rossmore Industrial Estate
Monaghan
Ireland

16. MANUFACTURER'S AUTHORISATION NUMBER(S)

EU/2/08/090/029 (1 syringe)
EU/2/08/090/030 (1 x 7 syringes)
EU/2/08/090/031 (1 x 14 syringes)

17. MANUFACTURER'S BATCH NUMBER

BN:

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Syringe labelling

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Loxicom 50 mg/g oral paste for horses
meloxicam

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Meloxicam 50 mg/g
Benzyl alcohol 10 mg/g

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER

8.4 g

4. METHOD AND ROUTE(S) OF ADMINISTRATION

Oral use

5. WITHDRAWAL PERIOD(S)

Meat and offal: 3 days.
Not authorised for use in animals producing milk for human consumption.

6. BATCH NUMBER

BN {number}

7. EXPIRY DATE

EXP {month/year}
Shelf life after first opening the immediate packaging: 28 days

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET:

Loxicom 0.5 mg/ml oral suspension for dogs

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder
Norbrook Laboratories (Ireland) Limited
Rossmore Industrial Estate
Monaghan
Ireland

Manufacturer responsible for batch release
Norbrook Manufacturing Limited
Rossmore Industrial Estate
Monaghan Town
Co. Monaghan
H18 W620
Ireland

Norbrook Laboratories Limited
105 Armagh Road
Newry
Co. Down, BT35 6PU
United Kingdom

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Loxicom 0.5 mg/ml oral suspension for dogs
meloxicam

3. STATEMENT OF THE ACTIVE SUBSTANCE AND OTHER INGREDIENTS

Each ml contains:

Meloxicam	0.5 mg
Sodium benzoate	1.5 mg

4. INDICATION(S)

Alleviation of inflammation and pain in both acute and chronic musculo-skeletal disorders.

5. CONTRAINDICATIONS

Do not use in pregnant or lactating animals.
Do not use in dogs suffering from gastrointestinal disorders such as irritation and haemorrhage, impaired hepatic, cardiac or renal function and haemorrhagic disorders.
Do not use in case of hypersensitivity to the active substance or to any of the excipients.

Do not use in dogs less than 6 weeks of age.

6. ADVERSE REACTIONS

Typical adverse reactions of non-steroidal anti-inflammatory drugs (NSAIDs) such as loss of appetite, vomiting, diarrhoea, faecal occult blood, apathy and renal failure have occasionally been reported. In very rare cases (less than 1 animal in 10,000 animals treated, including isolated reports), haemorrhagic diarrhoea, haematemesis, gastrointestinal ulceration and elevated liver enzymes have been reported.
These adverse reactions occur generally within the first treatment week and are in most cases transient and disappear following termination of the treatment but in very rare cases may be serious or fatal.
If adverse reactions occur, treatment should be discontinued and the advice of a veterinarian should be sought.

If you notice any side effects, even those not already listed in this package leaflet or you think that the medicine has not worked, please inform your veterinary surgeon.

7. TARGET SPECIES

Dogs.

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

Dosage:

Initial treatment is a single dose of 0.2 mg meloxicam/kg bodyweight (i.e. 4 ml/10 kg bodyweight) on the first day. Treatment is to be continued once daily by oral administration (at 24 hour intervals) at a maintenance dose of 0.1 mg meloxicam/kg bodyweight (i.e. 2 ml/10 kg bodyweight).

For longer term treatment, once clinical response has been observed (after ≥ 4 days), the dose can be adjusted to the lowest effective individual dose reflecting that the degree of pain and inflammation associated with chronic musculo-skeletal disorders may vary over time.

Method and route of administration:

Oral use.
To be administered with food or directly into the mouth.
Shake well before use.

The suspension can be given using either of the two measuring syringes provided in the package. The syringes fit onto the bottle and have a kg-bodyweight scale which corresponds to the maintenance dose (i.e. 0.1 mg meloxicam/kg bodyweight). Thus for initiation of the therapy on the first day, twice the maintenance volume will be required. Alternatively therapy may be initiated with Loxicom 5 mg/ml solution for injection.

A clinical response is normally seen within 3-4 days. Treatment should be discontinued after 10 days at the latest if no clinical improvement is apparent.

Avoid introduction of contamination during use.

9. ADVICE ON CORRECT ADMINISTRATION

Particular care should be taken with regard to the accuracy of dosing. Please carefully follow the instructions of the veterinarian.

10. WITHDRAWAL PERIOD(S)

Not applicable.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
This veterinary medicinal product does not require any special storage conditions.
Shelf-life after first opening the container: 6 months.
Do not use after the expiry date which is stated on the carton and the bottle after EXP.

12. SPECIAL WARNINGS

Special precautions for use in animals

If adverse reactions occur, treatment should be discontinued and the advice of a veterinarian should be sought. Avoid use in any dehydrated, hypovolaemic or hypotensive animal, as there is a potential risk of renal toxicity.
This product for dogs should not be used in cats due to the different dosing devices. In cats, Loxicom 0.5 mg/ml oral suspension for cats should be used.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:

People with known hypersensitivity to NSAIDs should avoid contact with the veterinary medicinal product.
In case of accidental ingestion, seek medical advice immediately and show this package leaflet or the label to the physician.

Pregnancy and lactation:
See section "Contraindications".

Interaction with other medicinal products and other forms of interaction

Other NSAIDs, diuretics, anticoagulants, aminoglycoside antibiotics and substances with high protein binding may compete for binding and thus lead to toxic effects. Loxicom must not be administered in conjunction with other NSAIDs or glucocorticosteroids.

Pre-treatment with anti-inflammatory substances may result in additional or increased adverse effects and accordingly a treatment-free period with such veterinary medicinal products should be observed for at least 24 hours before commencement of treatment. The treatment-free period, however, should take into account the pharmacokinetic properties of the products used previously.

Overdose (symptoms, emergency procedures, antidotes)

In the case of overdose, symptomatic treatment should be initiated.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Medicines should not be disposed of via wastewater or household waste. Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help to protect the environment.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

Detailed information on this veterinary medicinal product is available on the website of the European Medicines Agency http://www.ema.europa.eu/.

15. OTHER INFORMATION

The veterinary medicinal product is available in polyethylene terephthalate bottle of 15 and 30 ml with two (1 ml and a 5 ml syringe, are supplied with each bottle to ensure accurate dosing of small and large dogs) polyethylene/polypropylene measuring syringes.

Not all pack sizes may be marketed.

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder:

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NN18 9EX
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PACKAGE LEAFLET:
Loxicom 1.5 mg/ml oral suspension for dogs

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE IN THE EEA, IF DIFFERENT

Marketing authorisation holder
Norbrook Laboratories (Ireland) Limited
Rossmore Industrial Estate
Monaghan
Ireland

Manufacturer responsible for batch release
Norbrook Manufacturing Limited
Rossmore Industrial Estate
Monaghan Town
Co. Monaghan
H18 W620
Ireland

Norbrook Laboratories Limited
105 Armagh Road
Newry
Co. Down, BT35 6PU
United Kingdom

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Loxicom 1.5 mg/ml oral suspension for dogs
meloxicam

3. STATEMENT OF THE ACTIVE SUBSTANCE AND OTHER INGREDIENTS

Each ml contains:

Meloxicam	1.5 mg
Sodium benzoate	1.5 mg

Pale yellow suspension

4. INDICATION(S)

Alleviation of inflammation and pain in both acute and chronic musculo-skeletal disorders.

5. CONTRAINDICATIONS

Do not use in pregnant or lactating animals.
Do not use in dogs suffering from gastrointestinal disorders such as irritation and haemorrhage, impaired hepatic, cardiac or renal function and haemorrhagic disorders.

Do not use in case of hypersensitivity to the active substance or to any of the excipients.
Do not use in dogs less than 6 weeks of age.

6. ADVERSE REACTIONS

Typical adverse reactions of non-steroidal anti-inflammatory drugs (NSAIDs) such as loss of appetite, vomiting, diarrhoea, faecal occult blood, apathy and renal failure have occasionally been reported. In very rare cases (less than 1 animal in 10,000 animals treated, including isolated reports) haemorrhagic diarrhoea, haematemesis, gastrointestinal ulceration and elevated liver enzymes have been reported. These adverse reactions occur generally within the first treatment week and are in most cases transient and disappear following termination of the treatment but in very rare cases may be serious or fatal.
If adverse reactions occur, treatment should be discontinued and the advice of a veterinarian should be sought.

If you notice any side effects, even those not already listed in this package leaflet or you think that the medicine has not worked, please inform your veterinary surgeon.

7. TARGET SPECIES

Dogs.

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

Dosage:

Initial treatment is a single dose of 0.2 mg meloxicam/kg bodyweight (i.e. 1.33 ml/10 kg bodyweight) on the first day. Treatment is to be continued once daily by oral administration (at 24 hour interval) at a maintenance dose of 0.1 mg meloxicam/kg bodyweight (i.e. 0.667 ml/10 kg bodyweight).

For longer term treatment, once clinical response has been observed (after ≥ 4 days), the dose can be adjusted to the lowest effective individual dose reflecting that the degree of pain and inflammation associated with chronic musculo-skeletal disorders may vary over time.

Method and route of administration:

Oral use. To be administered with food or directly into the mouth. Shake well before use.

The suspension can be given using either of the two measuring syringes provided in the package. The syringes fit onto the bottle and have a kg-bodyweight scale which corresponds to the maintenance dose (i.e. 0.1 mg meloxicam/kg bodyweight). Thus for initiation of the therapy on the first day, twice the maintenance volume will be required.

Alternatively therapy may be initiated with Loxicom 5 mg/ml solution for injection.

A clinical response is normally seen within 3-4 days. Treatment should be discontinued after 10 days at the latest if no clinical improvement is apparent.

Avoid introduction of contamination during use.

9. ADVICE ON CORRECT ADMINISTRATION

Particular care should be taken with regard to the accuracy of dosing. Please carefully follow the instructions of the veterinarian.

10. WITHDRAWAL PERIOD(S)

Not applicable.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
Shelf-life after first opening the container: 6 months.
Do not use after the expiry date stated on the carton and the bottle.
This veterinary medicinal product does not require any special storage conditions.

12. SPECIAL WARNINGS

Special precautions for use in animals:

If adverse reactions occur, treatment should be discontinued and the advice of a veterinarian should be sought. Avoid use in any dehydrated, hypovolaemic or hypotensive animal, as there is a potential risk of renal toxicity.

Interaction with other medicinal products and other forms of interaction:

Other NSAIDs, diuretics, anticoagulants, aminoglycoside antibiotics and substances with high protein binding may compete for binding and thus lead to toxic effects. Loxicom must not be administered in conjunction with other NSAIDs or glucocorticosteroids.

Pre-treatment with anti-inflammatory substances may result in additional or increased adverse effects and accordingly a treatment-free period with such veterinary medicinal products should be observed for at least 24 hours before commencement of treatment. The treatment-free period, however, should take into account the pharmacokinetic properties of the products used previously.

Overdose (symptoms, emergency procedures, antidotes):

In the case of overdose symptomatic treatment should be initiated.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:

People with known hypersensitivity to NSAIDs should avoid contact with the veterinary medicinal product.
In case of accidental ingestion, seek medical advice immediately and show this package leaflet or the label to the physician.

Pregnancy and lactation
See section "Contraindications".

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, if any

Medicines should not be disposed of via wastewater or household waste. Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help to protect the environment.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST REVISED

Detailed information on this veterinary medicinal product is available on the website of the European Medicines Agency http://www.ema.europa.eu/.

15. OTHER INFORMATION

Polyethylene terephthalate bottle containing 10, 32, 100, 2 x 100 or 200 ml with two polyethylene/polypropylene measuring syringes. Not all pack sizes may be marketed.

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder

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PACKAGE LEAFLET:

Loxicom 5 mg/ml solution for injection for dogs and cats

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE IN THE EEA, IF DIFFERENT

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Manufacturer responsible for batch release
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2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Loxicom 5 mg/ml solution for injection for dogs and cats
meloxicam

3. STATEMENT OF THE ACTIVE SUBSTANCE AND OTHER INGREDIENTS

Each ml contains:

Meloxicam	5 mg
Ethanol, anhydrous	150 mg

Pale yellow solution

4. INDICATION(S)

Dogs:
Alleviation of inflammation and pain in both acute and chronic musculo-skeletal disorders. Reduction of post-operative pain and inflammation following orthopaedic and soft tissue surgery.

Cats:
Reduction of post-operative pain after ovariohysterectomy and minor soft tissue surgery.

5. CONTRAINDICATIONS

Do not use in pregnant or lactating animals.
Do not use in animals suffering from gastrointestinal disorders such as irritation and haemorrhage, impaired hepatic, cardiac or renal function and haemorrhagic disorders.
Do not use in case of hypersensitivity to the active substance or to any of the excipients.
Do not use in animals less than 6 weeks of age nor in cats of less than 2 kg.

6. ADVERSE REACTIONS

Typical adverse reactions of non-steroidal anti-inflammatory drugs NSAIDs such as loss of appetite, vomiting, diarrhoea, faecal occult blood, apathy and renal failure have occasionally been reported. In very rare cases elevated liver enzymes have been reported.

In very rare cases (less than 1 animal in 10,000 animals treated, including isolated reports), haemorrhagic diarrhoea, haematemesis and gastrointestinal ulceration have been reported.

These adverse reactions occur generally within the first treatment week and are in most cases transient and disappear following termination of the treatment but in very rare cases may be serious or fatal.

In very rare cases anaphylactoid reactions may occur and should be treated symptomatically.

If you notice any side effects, even those not already listed in this package leaflet or you think that the medicine has not worked, please inform your veterinary surgeon.

7. TARGET SPECIES

Dogs and cats.

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

Dosage for each species:

Dogs:
Single administration of 0.2 mg meloxicam/kg bodyweight (i.e. 0.4 ml/10 kg).

Cats:
Single administration of 0.3 mg meloxicam/kg bodyweight (i.e. 0.06 ml/kg) where no oral follow-up treatment is possible e.g. feral cats.
Single administration of 0.2 mg meloxicam/kg bodyweight (i.e. 0.04 ml/kg) when administration of meloxicam is to be continued as an oral follow-up therapy

Method and route of administration:

Dogs:
Musculo-skeletal disorders: single subcutaneous injection.
Loxicom 1.5 mg/ml oral suspension or Loxicom 0.5 mg/ml oral suspension may be used for continuation of treatment at a dosage of 0.1 mg meloxicam/kg bodyweight, 24 hours after administration of the injection.
Reduction of post-operative pain (over a period of 24 hours): single intravenous or subcutaneous injection before surgery, for example at the time of induction of anaesthesia.

Cats:
Reduction of post-operative pain in cats where no oral follow-up treatment is possible e.g. feral cats: Single subcutaneous injection at a dosage of 0.3 mg meloxicam/kg bodyweight (i.e. 0.06 ml/kg bodyweight) before surgery, for example at the time of induction of anaesthesia. In this case do not use oral follow up treatment.

Reduction of post-operative pain in cats when administration of meloxicam is to be continued as an oral follow-up therapy:
Single subcutaneous injection at a dosage of 0.2 mg meloxicam/kg body weight (i.e. 0.04 ml/kg body weight) before surgery, for example at the time of induction of anaesthesia.
To continue treatment for up to five days, this initial dose may be followed 24 hours later by administration of Loxicom 0.5 mg/ml oral suspension for cats at a dosage of 0.05 mg meloxicam/kg body weight. The oral follow-up dose may be administered for up to a total of four doses at 24 hour intervals.

Avoid introduction of contamination during use.

9. ADVICE ON CORRECT ADMINISTRATION

Particular care should be taken with regard to the accuracy of dosing.

A suitably graduated 1 ml syringe should be used for administration of the product to cats.

10. WITHDRAWAL PERIOD(S)

Not applicable.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
This veterinary medicinal product does not require any special storage conditions.
Shelf-life after first opening the container: 28 days.
Do not use after the expiry date stated on the carton and the bottle.

12. SPECIAL WARNING(S)

For post-operative pain relief in cats, safety has only been documented after thiopental/halothane anaesthesia.

Special precautions for use in animals:
If adverse effects occur, treatment should be discontinued and the advice of a veterinarian should be sought.
Avoid use in any dehydrated, hypovolaemic or hypotensive animal, as there is a potential risk of increased renal toxicity.
During anaesthesia, monitoring and fluid therapy should be considered as standard practice.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
Accidental self-injection may give rise to pain. People with known hypersensitivity to NSAIDs should avoid contact with the veterinary medicinal product.

In case of accidental self-injection, seek medical advice immediately and show this package leaflet or the label to the physician.

Pregnancy and lactation:
See section "Contraindications".

Interaction with other medicinal products and other forms of interaction:
Other NSAIDs, diuretics, anticoagulants, aminoglycoside antibiotics and substances with high protein binding may compete for binding and thus lead to toxic effects. Loxicom must not be administered in conjunction with other NSAIDs or glucocorticosteroids. Concurrent administration of potential nephrotoxic drugs should be avoided. In animals at anaesthetic risk (e.g. aged animals) intravenous or subcutaneous fluid therapy during anaesthesia should be taken into consideration. When anaesthesia and NSAID are concomitantly administered, a risk for renal function cannot be excluded.
Pre-treatment with anti-inflammatory substances may result in additional or increased adverse effects and accordingly a treatment-free period with such drugs should be observed for at least 24 hours before commencement of treatment. The treatment-free period, however, should take into account the pharmacokinetic properties of the products used previously.

Overdose (symptoms, emergency procedures, antidotes):
In the case of overdose symptomatic treatment should be initiated.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, if any

Medicines should not be disposed of via wastewater or household waste. Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help to protect the environment.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

Detailed information on this veterinary medicinal product is available on the website of the European Medicines Agency http://www.ema.europa.eu/.

15. OTHER INFORMATION

10 ml, 20 ml or 100 ml injection vial.
Not all pack sizes may be marketed.

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder

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Loxicom 0.5 mg/ml oral suspension for cats

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder
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Rossmore Industrial Estate
Monaghan
Ireland

Manufacturer responsible for batch release
Norbrook Manufacturing Limited
Rossmore Industrial Estate
Monaghan Town
Co. Monaghan
H18 W620
Ireland

Norbrook Laboratories Limited
105 Armagh Road
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Co. Down, BT35 6PU
United Kingdom

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Loxicom 0.5 mg/ml oral suspension for cats.
meloxicam

3. STATEMENT OF THE ACTIVE SUBSTANCE AND OTHER INGREDIENTS

Each ml contains
Active Substance:
Meloxicam 0.5 mg

Excipient:
Sodium benzoate 1.5 mg

Pale yellow suspension.

4. INDICATION(S)

Alleviation of mild to moderate post-operative pain and inflammation following surgical procedures in cats, e.g. orthopaedic and soft tissue surgery.
Alleviates inflammation and pain in acute and chronic musculo-skeletal disorders in cats.

5. CONTRAINDICATIONS

Do not use in pregnant or lactating animals.
Do not use in cats suffering from gastrointestinal disorders such as irritation and haemorrhage, impaired hepatic, cardiac or renal function and haemorrhagic disorders.
Do not use in case of hypersensitivity to the active substance or to any of the excipients.
Do not use in cats less than 6 weeks old.

6. ADVERSE REACTIONS

Typical adverse drug reactions of NSAIDS such as loss of appetite, vomiting, diarrhoea, faecal occult blood, lethargy and renal failure have occasionally been reported. In very rare cases (less than 1 animal in 10,000 animals treated, including isolated reports) gastrointestinal ulceration and elevated liver enzymes have been reported.
These side effects are in most cases transient and disappear following termination of the treatment but in very rare cases may be serious or fatal.

If adverse reactions occur, treatment should be discontinued and the advice of a veterinarian should be sought.

If you notice any side effects, even those not already listed in this package leaflet or you think that the medicine has not worked, please inform your veterinary surgeon.

7. TARGET SPECIES

Cats.

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

Dosage
Post-operative pain and inflammation following surgical procedures:
After initial treatment with Loxicom 5 mg/ml Solution for Injection for Dogs and Cats continue treatment 24 hours later with Loxicom 0.5 mg/ml oral suspension for cats at a dosage of 0.05 mg meloxicam/kg body weight. The oral follow-up dose may be administered once daily (at 24-hour intervals) for up to four days.

Acute musculo-skeletal disorders:
Initial treatment is a single oral dose of 0.2 mg meloxicam/kg body weight on the first day. Treatment is to be continued once daily by oral administration (at 24-hour intervals) at a dose of 0.05 mg meloxicam/kg body weight for as long as acute pain and inflammation persist.

Chronic musculo-skeletal disorders:
Initial treatment is a single oral dose of 0.1 mg meloxicam/kg body weight on the first day. Treatment is to be continued once daily by oral administration (at 24 hour intervals) at a maintenance dose of 0.05 mg meloxicam/kg body weight.
A clinical response is normally seen within 7 days. Treatment should be discontinued after 14 days at the latest if no clinical improvement is apparent.

Route and method of administration
The recommended dose should not be exceeded. Loxicom 0.5 mg/ml Oral Suspension for Cats is to be administered orally either mixed with food or directly into the mouth. The suspension is given using the Loxicom measuring syringe provided in the package. The syringe fits onto the bottle and has a kg-body weight scale which corresponds to the maintenance dose. Thus for initiation of the treatment of chronic musculo-skeletal disorders on the first day, twice the maintenance volume will be

required. For initiation of the treatment of acute musculo-skeletal disorders on the first day, 4 times the maintenance volume will be required.

9. ADVICE ON CORRECT ADMINISTRATION

Meloxicam has a narrow therapeutic safety margin in cats and clinical signs of overdose may be seen at relatively small overdose levels. To ensure administration of a correct dose, body weight should be determined as accurately as possible.
Please carefully follow the instructions of the veterinarian.
Shake well before use.
Avoid introduction of contamination during use.

10. WITHDRAWAL PERIOD(S)

Not applicable.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
This veterinary medicinal product does not require any special storage conditions.
Shelf life after first opening the container: 6 months
Do not use after the expiry date stated on the carton and the bottle after EXP.

12. SPECIAL WARNINGS

Special precautions for use in animals:

If adverse reactions occur, treatment should be discontinued and the advice of a veterinarian should be sought.
Avoid use in any dehydrated, hypovolaemic or hypotensive animal, as there is a potential risk of renal toxicity.

Post-operative pain and inflammation following surgical procedures:
In case additional pain relief is required, multimodal pain therapy should be considered.

Chronic musculoskeletal disorders:
Response to long-term therapy should be monitored at regular intervals by a veterinary surgeon.

Treatment should be discontinued after 14 days at the latest if no clinical improvement is apparent.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:

People with known hypersensitivity to NSAIDs should avoid contact with the veterinary medicinal product.
In case of accidental ingestion, seek medical advice immediately and show the package leaflet or label to the physician.

Pregnancy and lactation
See section "Contraindications".

Interaction with other medicinal products and other forms of interaction:

Other NSAIDs, diuretics, anticoagulants, aminoglycoside antibiotics and substances with high protein binding may compete for binding and thus lead to toxic effects. Loxicom must not be administered in conjunction with other NSAIDs or glucocorticosteroids. Concurrent administration of potential nephrotoxic drugs should be avoided.
Pre-treatment with anti-inflammatory substances may result in additional or increased adverse effects and accordingly a treatment-free period with such drugs should be observed for at least 24 hours before commencement of treatment with Loxicom. The treatment free period, however, should take into account the pharmacological properties of the products used previously.

Overdose (symptoms, emergency procedures, antidotes):
Meloxicam has a narrow therapeutic safety margin in cats and clinical signs of overdose may be seen at relatively small overdose levels.
In case of overdose, adverse reactions, as listed in section "Adverse reactions", are expected to be more severe and more frequent. In case of overdose symptomatic treatment should be initiated.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Medicines should not be disposed of via wastewater or household waste. Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help to protect the environment.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

Detailed information on this veterinary medicinal product is available on the website of the European Medicines Agency http://www.ema.europa.eu/.

15. OTHER INFORMATION

Mode of Action

Meloxicam is a non-steroidal anti-inflammatory drug (NSAID) of the oxicam class which acts by inhibition of prostaglandin synthesis, thereby exerting anti-inflammatory, analgesic, anti-exudative and antipyretic effects. It reduces leukocyte infiltration into the inflamed tissue. To a minor extent it also inhibits collagen-induced thrombocyte aggregation. *In vitro* and *in vivo* studies demonstrated that meloxicam inhibits cyclooxygenase-2 (COX-2) to a greater extent than cyclooxygenase-1 (COX-1).

Pack size

Loxicom 0.5 mg/ml Oral Suspension for Cats is available in bottle of 5 ml, 15 ml and 30 ml volumes.

Not all pack sizes may be marketed.

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

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PACKAGE LEAFLET:

Loxicom 20 mg/ml solution for injection for cattle, pigs and horses

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE IN THE EEA, IF DIFFERENT

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2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Loxicom 20 mg/ml solution for injection for cattle, pigs and horses
meloxicam

3. STATEMENT OF THE ACTIVE SUBSTANCE AND OTHER INGREDIENTS

One ml contains:
Meloxicam 20 mg
Ethanol 150mg

A yellow solution.

4. INDICATIONS

Cattle:
For use in acute respiratory infection with appropriate antibiotic therapy to reduce clinical signs in cattle.
For use in diarrhoea in combination with oral re-hydration therapy to reduce clinical signs in calves of over one week of age and young, non-lactating cattle.
For adjunctive therapy in the treatment of acute mastitis, in combination with antibiotic therapy.
For the relief of post-operative pain following dehorning in calves.

Pigs:
For use in non-infectious locomotor disorders to reduce the symptoms of lameness and inflammation.
For adjunctive therapy in the treatment of puerperal septicaemia and toxaemia (mastitis-metritis-agalactia syndrome) with appropriate antibiotic therapy.

Horses:
For use in the alleviation of inflammation and relief of pain in both acute and chronic musculo-skeletal disorders.
For the relief of pain associated with equine colic.

5. CONTRAINDICATIONS

Do not use in horses less than 6 weeks of age.
Do not use in pregnant or lactating mares.
Do not use in animals suffering from impaired hepatic, cardiac or renal function and haemorrhagic disorders, or where there is evidence of ulcerogenic gastrointestinal lesions.
Do not use in case of hypersensitivity to the active substance or to any of the excipients.
For the treatment of diarrhoea in cattle, do not use in animals of less than one week of age.

6. ADVERSE REACTIONS

Administration of the product by the subcutaneous route in cattle and the intramuscular route in pigs is well tolerated; only a slight transient swelling at the injection site following subcutaneous administration was observed in cattle treated in clinical studies.

In horses, transient swellings at the injection site can occur but resolves without intervention.

In very rare cases (less than 1 animal in 10,000 animals treated, including isolated reports), anaphylactoid reactions which may be serious (including fatal), may occur and should be treated symptomatically.

If you notice any side effects, even those not already listed in this package leaflet or you think that the medicine has not worked, please inform your veterinary surgeon.

7. TARGET SPECIES

Cattle, pigs and horses**.**

8. DOSAGE FOR EACH SPECIES, METHOD AND ROUTE(S) OF ADMINISTRATION

Cattle:
Single subcutaneous or intravenous injection at a dosage of 0.5 mg meloxicam/kg body weight (i.e., 2.5 ml/100 kg body weight) in combination with antibiotic therapy or with oral re-hydration therapy, as appropriate. The recommended maximum volume to be administered at a single injection site is 10 ml.

Pigs:
Single intramuscular injection at a dosage of 0.4 mg meloxicam/kg body weight (i.e., 2.0 ml/100 kg body weight) in combination with antibiotic therapy, as appropriate. If required, a second administration of meloxicam can be given after 24 hours. The recommended maximum volume to be administered at a single injection site is 2 ml.

Horses:
Single intravenous injection as a dosage of 0.6 mg meloxicam/kg body weight (i.e., 3.0 ml/100 kg body weight).

For use in the alleviation of inflammation and the relief of pain in both acute and chronic musculoskeletal disorders, a suitable oral therapy containing meloxicam, administered in accordance with label recommendations, may be used for continuation of treatment.

Do not exceed 50 broachings per vial. If more than 50 broachings are required, the use of a draw-off needle is recommended.

9. ADVICE ON CORRECT ADMINISTRATION

Avoid introduction of contamination during use.

10. WITHDRAWAL PERIOD(S)

Cattle:	Meat and offal:	15 days	Milk:	5 days
Pigs:	Meat and offal:	5 days		
Horses:	Meat and offal:	5 days.		

Not authorised for use in horses producing milk for human consumption.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
This veterinary medicinal product does not require any special storage conditions.
Shelf life after first broaching the glass vial: 28 days.
Do not use after the expiry date (EXP) stated on the carton and vial after EXP.

12. SPECIAL WARNINGS

Treatment of calves with Loxicom 20 minutes before dehorning reduces post-operative pain. Loxicom alone will not provide adequate pain relief during the dehorning procedure. To obtain adequate pain relief during surgery co-medication with an appropriate analgesic is needed.

Special precautions for use in animals:
If adverse reactions occur, treatment should be discontinued and the advice of a veterinarian should be sought.
Avoid use in very severely dehydrated, hypovolaemic or hypotensive animals which require parenteral rehydration, as there may be a potential risk of renal toxicity.
In case of inadequate relief of pain when used in the treatment of equine colic, careful re-evaluation of the diagnosis should be made as this could indicate the need for surgical intervention.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
Accidental self-injection may give rise to pain. People with known hypersensitivity to Non-Steroidal Anti-Inflammatory Drugs (NSAIDs) should avoid contact with the veterinary medicinal product.
In case of accidental self-injection, seek medical advice immediately and show this package leaflet or the label to the physician.

Use during pregnancy and lactation:
Cattle and pigs**:** Can be used during pregnancy and lactation.
Horses: See section "Contraindications".

Interaction with other medicinal products and other forms of interaction:
Do not administer concurrently with glucocorticosteroids, other non-steroidal anti-inflammatory drugs or with anti-coagulant agents.

Overdose (symptoms, emergency procedures, antidotes):
In the case of overdose, symptomatic treatment should be initiated.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Any unused medicines or waste materials should not be disposed of via wastewater or household waste but in accordance with local requirements. Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help to protect the environment.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

Detailed information on this veterinary medicinal product is available on the website of the European Medicines Agency http://www.ema.europa.eu/.

15. OTHER INFORMATION

Cardboard box with either 1 or 12 colourless glass injection vial(s) each containing 30, 50 or 100 ml.
Cardboard box with 1, 6 or 12 colourless glass injection vial(s) each containing 250 ml.
Not all pack sizes may be marketed

Each vial is closed with a bromobutyl bung and sealed with an aluminium cap.

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder

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PACKAGE LEAFLET
Loxicom 1 mg chewable tablets for dogs
Loxicom 2.5 mg chewable tablets for dogs

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder:
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Rossmore Industrial Estate
Monaghan
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Manufacturer responsible for batch release:
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Rossmore Industrial Estate
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Co. Monaghan
H18 W620
Ireland

Norbrook Laboratories Limited
105 Armagh Road,
Newry,
Co. Down,
BT35 6PU
United Kingdom

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Loxicom 1 mg chewable tablets for dogs.
Loxicom 2.5 mg chewable tablets for dogs.
meloxicam

3. STATEMENT OF THE ACTIVE SUBSTANCE AND OTHER INGREDIENTS

One chewable tablet contains:
Meloxicam 1 mg
Meloxicam 2.5 mg

Light brown oval biconvex tablet with a score line on one face and plain on the other. The tablet can be divided into equal halves.

4. INDICATION(S)

Alleviation of inflammation and pain in both acute and chronic musculo-skeletal disorders in dogs.

5. CONTRAINDICATIONS

Do not use in pregnant or lactating animals.
Do not use in animals suffering from gastrointestinal disorders such as irritation and haemorrhage, impaired hepatic, cardiac or renal function and haemorrhagic disorders.
Do not use in dogs less than 6 weeks of age or less than 4 kg body weight.
Do not use in case of hypersensitivity to the active substance or to any of the excipients.

6. ADVERSE REACTIONS

Typical adverse drug reactions of non-steroidal anti-inflammatory drugs (NSAIDs) such as loss of appetite, vomiting, diarrhoea, faecal occult blood, apathy and renal failure have occasionally been reported. In very rare cases (less than 1 animal in 10,000 animals treated, including isolated reports), haemorrhagic diarrhoea, haematemesis, gastrointestinal ulceration and elevated liver enzymes have been reported. These side effects occur generally within the first treatment week and are in most cases transient and disappear following termination of the treatment but in very rare cases may be serious or fatal.

If you notice any side effects, even those not already listed in this package leaflet or you think that the medicine has not worked, please inform your veterinary surgeon.

7. TARGET SPECIES

Dogs.

8. DOSAGE FOR EACH SPECIES, ROUTE AND METHOD OF ADMINISTRATION

Initial treatment is a single dose of 0.2 mg meloxicam/kg body weight on the first day, which can be given orally or alternatively using meloxicam 5 mg/ml solution for injection for dogs and cats.
Treatment is to be continued once daily by oral administration (at 24-hour intervals) at a maintenance dose of 0.1 mg meloxicam/kg body weight. Alternatively, therapy may be initiated with a solution for injection containing 5 mg meloxicam/ml.
Each chewable tablet contains either 1 mg or 2.5 mg meloxicam, which corresponds to the daily maintenance dose for a 10 kg body weight dog or a 25 kg body weight dog, respectively.
Each chewable tablet can be halved for accurate dosing according to the individual body weight of the animal. The veterinary medicinal product can be administered with or without food, are flavoured and are taken by most dogs voluntarily.

Dose scheme for the maintenance dose:

Body weight (kg)	Number of chewable tablets 1 mg	Number of chewable tablets 2.5 mg	mg/kg
4.0-7.0	½		0.13-0.1
7.1-10.0	1		0.14-0.1
10.1-15.0	1½		0.15-0.1
15.1-20.0	2		0.13-0.1
20.1-25.0		1	0.12-0.1
25.1-35.0		1½	0.15-0.1
35.1-50.0		2	0.14-0.1

The use of a meloxicam containing oral suspension for dogs may be considered for an even more precise dosing. For dogs weighing less than 4 kg the use of meloxicam containing oral suspension for dogs is recommended.
A clinical response is normally seen within 3-4 days. Treatment should be discontinued after 10 days if no clinical improvement is apparent.

9. ADVICE ON CORRECT ADMINISTRATION

To ensure correct dosage, bodyweight should be determined as accurately as possible to avoid underdosing or overdosing.

10. WITHDRAWAL PERIOD(S)

Not applicable.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

Do not store above 25°C.
Store in the original package in order to protect from light.
Shelf-life of the halved tablet: 24-hours

Do not use this veterinary medicinal product after the expiry date which is stated on the carton and the blister after EXP.

12. SPECIAL WARNINGS

Special precautions for use in animals:
If adverse reactions occur, treatment should be discontinued and the advice of a veterinarian should be sought.
Avoid use in any dehydrated, hypovolaemic or hypotensive animal, as there is a potential risk of renal toxicity.
This veterinary medicinal product for dogs should not be used in cats as it is not suitable for use in this species. In cats, a meloxicam containing oral suspension authorised for that species should be used.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
People with known hypersensitivity to non-steroidal anti-inflammatory drugs (NSAIDs) should avoid contact with the veterinary medicinal product.
In case of accidental ingestion, seek medical advice immediately and show the package leaflet or the label to the physician.

Pregnancy and lactation:
See section "Contraindications".

Interaction with other medicinal products and other forms of interaction:
Other non-steroidal anti-inflammatory drugs (NSAIDs), diuretics, anticoagulants, aminoglycoside antibiotics and substances with high protein binding may compete for binding and thus lead to toxic effects. Loxicom must not be administered in conjunction with other NSAIDs or glucocorticosteroids.

Pre-treatment with anti-inflammatory substances may result in additional or increased adverse effects and accordingly a treatment-free period with such drugs should be observed for at least 24 hours before commencement of treatment. The treatment-free period, however, should take into account the pharmacological properties of the products used previously.

Overdose (symptoms, emergency procedures, antidotes):
In case of overdose symptomatic treatment should be initiated.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Any unused medicines or waste materials should not be disposed of via wastewater or household waste but in accordance with local requirements. Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help to protect the environment.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

Detailed information on this veterinary medicinal product is available on the website of the European Medicines Agency http://www.ema.europa.eu/.

15. OTHER INFORMATION

Blister packs of 10 tablets per strip in cartons containing 10, 20, 100 or 500 tablets.

Not all pack sizes may be marketed.

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder

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PACKAGE LEAFLET:
Loxicom 50 mg/g oral paste for horses

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder:
Norbrook Laboratories (Ireland) Limited
Rossmore Industrial Estate
Monaghan
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Manufacturer responsible for batch release:
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Rossmore Industrial Estate
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Norbrook Laboratories Limited
105 Armagh Road
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Co. Down, BT35 6PU
United Kingdom

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Loxicom 50 mg/g oral paste for horses
meloxicam

3. STATEMENT OF THE ACTIVE SUBSTANCE AND OTHER INGREDIENTS

One gram contains:

Active substance:

Meloxicam 50 mg

Excipient:

Benzyl Alcohol 10 mg

A pale yellow homogenous paste.

4. INDICATION(S)

Alleviation of inflammation and relief of pain in both acute and chronic musculo-skeletal disorders in horses.

5. CONTRAINDICATIONS

Do not use in pregnant or lactating mares.
Do not use in horses suffering from gastrointestinal disorders such as irritation and haemorrhage, impaired hepatic, cardiac or renal function and haemorrhagic disorders.
Do not use in case of hypersensitivity to the active substance or to any of the excipients.
Do not use in horses less than 6 weeks of age.

6. ADVERSE REACTIONS

Isolated cases of adverse reactions typically associated with NSAIDs were observed in clinical trials (slight urticaria, diarrhoea). Symptoms were reversible. Commonly, a reduction in blood albumin concentration will occur during the period of treatment (up to 14 days). In very rare cases (less than 1 animal in 10,000 animals treated, including isolated reports) loss of appetite, lethargy, abdominal pain and colitis have been reported. In very rare cases anaphylactoid reactions, which may be serious (including fatal), may occur and should be treated symptomatically. If adverse reactions occur, treatment should be discontinued and the advice of a veterinarian should be sought.

If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked please inform your veterinary surgeon.

7. TARGET SPECIES

Horses**.**

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

Administer 0.6 mg/kg body weight, once daily for up to 14 days.
To be administered directly into the mouth over the back of the tongue keeping the animal's head raised until swallowed.

One syringe division of paste should be administered per 50 kg bodyweight. The syringe has an integrated adapter and has a kg/body weight graduation.
Each syringe delivers 420 mg meloxicam, sufficient to treat 700 kg of bodyweight.

9. ADVICE ON CORRECT ADMINISTRATION

Avoid introduction of contamination during use.

10. WITHDRAWAL PERIOD(S)

Meat and offal: 3 days.
Not authorised for use in animals producing milk for human consumption.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
Store below 30ºC
Do not use after the expiry date (EXP) stated on the carton and syringe.
Shelf life after first opening the immediate packaging: 28 days

12. SPECIAL WARNING(S)

Special precautions for use in animals:
Avoid use in any dehydrated, hypovolaemic or hypotensive animals as there is a potential risk of renal toxicity.
Do not exceed the recommended dose or duration of treatment due to the possibility of severe adverse reactions.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
People with known hypersensitivity to Non-Steroidal Anti-Inflammatory Drugs (NSAIDs) should avoid contact with the veterinary medicinal product.
Avoid skin and eye contact with the product. If skin and/or eye contact occurs, wash the affected parts immediately with water. Should irritation occur and persist, seek medical advice.
In case of accidental ingestion, seek medical advice immediately and show the package leaflet or the label to the physician.

Use during pregnancy and lactation:
Do not use in pregnant or lactating mares

Interaction with other medicinal products and other forms of interaction:
Do not administer concurrently with glucocorticosteroids, other non-steroidal anti-inflammatory drugs or with anti-coagulant agents.

Overdose (symptoms, emergency procedures, antidotes):
The following clinical signs (some of which may be serious) have been reported in clinical studies following administration of the product at 5x overdose: dull behaviour, diarrhoea, oedema, buccal mucosal ulceration and/or dark coloured urine.
In case of overdose, symptomatic treatment should be initiated.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Medicines should not be disposed of via wastewater or household waste. Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help to protect the environment.

14. DATE ON WHICH THE PACKAGE INSERT WAS LAST REVISED

Detailed information on this product is available on the website of the European Medicines Agency http://www.ema.europa.eu/.

15. OTHER INFORMATION

For animal treatment only. To be supplied only on veterinary prescription.

The oral paste is available in the following pack sizes:
- 1 carton box containing 1 syringe

- 1 carton box containing 7 syringes
- 1 carton box containing 14 syringes

Not all pack sizes may be marketed

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder

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