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 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.

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

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 Limited
Station Works
Camlough Road
Newry
Co. Down
BT35 6JP

16. MARKETING AUTHORISATION NUMBER(S)

Vm 02000/5006

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 Limited
Station Works
Camlough Road
Newry
Co. Down
BT35 6JP

16. MARKETING AUTHORISATION NUMBER(S)

Vm 02000/5006

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.

B. PACKAGE LEAFLET

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

Marketing authorisation holder
Norbrook Laboratories Limited
Station Works
Camlough Road
Newry
Co. Down
BT35 6JP

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 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

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

United Kingdom
Norbrook Laboratories (GB) Ltd
1 Saxon Way East
Oakley Hay Industrial Estate
Corby
Northamptonshire
NN18 9EX
United Kingdom

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