ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

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

16. MARKETING AUTHORISATION NUMBER(S)

Vm 02000/5000

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.

PACKAGE LEAFLET:

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
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 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.
This product can cause eye irritation. In case of contact with the eyes, immediately rinse thoroughly with water.
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. PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

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.

United Kingdom
Norbrook Laboratories Limited
Carnbane Industrial Estate
Newry
BT35 6QQ, Co Down
Northern Ireland

Gavin Hall

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