PARTICULARS TO APPEAR ON THE OUTER PACKAGE
Carton box 10 ml, 20 ml and 100m l bottle

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Norbrook Meloxicam 5 mg/ml solution for injection for dogs and cats
Meloxicam

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:
Meloxicam 5 mg

3. PHARMACEUTICAL FORM

Solution for injection.

4. PACKAGE SIZE

10 ml
20 ml.
100 ml

5. TARGET SPECIES

Dogs and cats.

6. 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.

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

Not applicable.

9. SPECIAL WARNING(S), IF NECESSARY

Do not use in pregnant or lactating animals.
Pregnant women should not administer this product.

10. EXPIRY DATE

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

11. SPECIAL STORAGE CONDITIONS

Store below 25 °C.
Keep the vial in the outer carton in order to protect from light.

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

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

[Distribution category]

For animal treatment only.

POM-V 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
Newry
Co. Down, BT35 6JP
United Kingdom

DISTRIBUTED BY:
Norbrook Laboratories Ltd.
Carnbane Industrial Estate,
Newry,
Co Down,
BT35 6QQ,
Northern Ireland

16. MARKETING AUTHORISATION NUMBER

Vm 02000/4397

POM-V Prescription Only Medicine – Veterinarian
To be supplied only on veterinary prescription

17. MANUFACTURER'S BATCH NUMBER

B.N.:

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE
100m l bottle

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Norbrook Meloxicam 5 mg/ml solution for injection for dogs and cats
meloxicam

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:
Meloxicam 5 mg

3. PHARMACEUTICAL FORM

Solution for injection.

4. PACKAGE SIZE

100 ml

5. TARGET SPECIES

Dogs and cats.

6. 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.

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

Not applicable.

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

Store below 25 °C.
Keep the vial in the outer carton in order to protect from light.
Once broached, use by…….

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

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.

POM-V 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
Newry
Co. Down, BT35 6JP
United Kingdom

16. MARKETING AUTHORISATION NUMBER

Vm 02000/4397

17. MANUFACTURER'S BATCH NUMBER

B.N.:

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS 10 and 20 ml bottle

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Norbrook Meloxicam 5 mg/ml solution for injection for dogs and cats
Meloxicam

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Meloxicam 5 mg/ml

3. CONTENTS 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

Not applicable.

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.

[Include information under these headings as it appears in the SPC]
PACKAGE LEAFLET FOR:

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
Newry
Co. Down, BT35 6JP
United Kingdom

Manufacturer responsible for batch release
Norbrook Laboratories Limited
105 Armagh Road
Newry
Co. Down, BT35 6PU
United Kingdom

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Norbrook Meloxicam 5 mg/ml solution for injection for dogs and cats
Meloxicam

3. STATEMENT OF THE ACTIVE SUBSTANCE (S) 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 been reported very rarely in spontaneous reports. Elevated liver enzymes have been reported very rarely in spontaneous reports. In dogs, haemorrhagic diarrhoea, haematemesis and gastrointestinal ulceration have been reported very rarely in spontaneous reports.
In dogs, 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.
Anaphylactoid reactions may occur very rarely in spontaneous reports 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).

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.
A Meloxicam 1.5 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 a Meloxicam 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.
Store below 25 °C.
Keep the vial in the outer carton in order to protect from light.
Shelf-life after first opening the container: 28 days.
When the container is broached/opened for the first time, using the in-use shelf-life which is specified on this package leaflet, the date on which any product remaining in the vial should be discarded should be determined. This discard date should be written in the space provided on the vial.
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.

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. Meloxicam 5 mg/ml solution for injection 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 pharmacological 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:
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.

In view of the risk of accidental self-injection and the known adverse class-effects of NSAIDs and other prostaglandin inhibitors on pregnancy and/or embryofoetal development, the veterinary medicinal product should not be administered by pregnant women or women attempting to conceive.

This product can cause eye irritation. In case of contact with the eyes, immediately rinse thoroughly with water.

Wash hands after use.

Pregnancy and lactation:
The safety of the veterinary medicinal product has not been established during pregnancy and lactation. See also the contraindications section of this package leaflet.

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

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

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

November 2023

15. OTHER INFORMATION

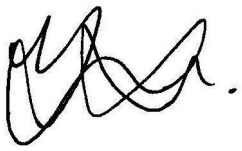
Vm 02000/4397

POM-V Prescription Only Medicine – Veterinarian
To be supplied only on veterinary prescription

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:

DISTRIBUTOR
Norbrook Laboratories Ltd.
Carnbane Industrial Estate
Newry, Co Down
BT35 6QQ
Northern Ireland



Approved: 16 April 2024