

**PARTICULARS TO APPEAR ON THE OUTER PACKAGE**  
**Carton box 5 ml, 15 ml and 30 ml bottle**

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Norbrook Meloxicam 0.5mg/ml Oral Suspension for Cats

**2. STATEMENT OF ACTIVE SUBSTANCES**

Meloxicam: 0.5 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**

Oral use.

Shake well before use.

To be administered orally either mixed with food or directly into the mouth using the Norbrook Meloxicam measuring syringe provided.

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.

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 cats less than 6 weeks old.

## 10. EXPIRY DATE

EXP:

Shelf-life of opened bottle: 6 months.

## 11. SPECIAL STORAGE CONDITIONS

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

## 12. SPECIFIC 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

*[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  
Newry  
Co. Down  
United Kingdom  
Telephone number: 02830260200  
Fax number: 02830260201

### **DISTRIBUTED BY:**

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

## 16. MARKETING AUTHORISATION NUMBER

Vm 02000/4395

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

**17. MANUFACTURER'S BATCH NUMBER**

B.N.:

**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**

Norbrook Meloxicam 0.5mg/ml Oral Suspension for Cats

**2. QUANTITY OF THE ACTIVE SUBSTANCE(S)**

Meloxicam 0.5 mg/ml

**3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES**

5 ml, 15 ml and 30 ml

**4. ROUTE(S) OF ADMINISTRATION**

Oral use.

Shake well before use.

To be administered with food or directly into the mouth using the Norbrook Meloxicam measuring syringe provided.

Avoid introduction of contamination during use.

Read the package leaflet before use.

**5. WITHDRAWAL PERIOD**

Not applicable.

**6. BATCH NUMBER**

BN:

**7. EXPIRY DATE**

EXP:

Shelf-life of opened bottle: 6 months.

Once opened, use by.....

**8. THE WORDS "FOR ANIMAL TREATMENT ONLY"**

For animal treatment only.

To be supplied only on veterinary prescription.

**[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 0.5mg/ml Oral Suspension for Cats

**3. STATEMENT OF THE ACTIVE SUBSTANCE (S) AND OTHER INGREDIENTS**

Each ml contains 0.5 mg of Meloxicam and 1.5 mg of Sodium Benzoate.  
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**

Should not be used in pregnant or lactating animals.  
Should not be used in animals suffering from gastrointestinal disorders such as irritation and haemorrhage, impaired hepatic, cardiac or renal function and haemorrhagic disorders.  
Should not be used in case of hypersensitivity to the active substance or to any of the excipients.  
Should not be used 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, apathy and renal failure have been reported very rarely in spontaneous reports. Elevated liver enzymes have been reported very rarely in spontaneous reports.

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.

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

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 Norbrook Meloxicam 0.5mg/ml Oral Suspension for Cats continue.

treatment 24 hours later with Norbrook 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 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. Norbrook Meloxicam 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 Norbrook Meloxicam 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. Shake well before use.

### **9. ADVICE ON CORRECT ADMINISTRATION**

Particular care should be taken with regard to the accuracy of dosing. To ensure administration of a correct dose, body weight should be determined as accurately as possible.

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.

Do not use this veterinary medicinal product after the expiry date which is stated on the label.

Shelf life after first opening the container: 6 months

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 bottle should be discarded should be determined. This discard date should be written in the space provided on the bottle.

### **12. SPECIAL WARNING(S)**

#### 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.

Pregnancy and lactation:

The safety of the veterinary medicinal product has not been established during pregnancy and lactation.

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 label to the physician.

Wash any splashes from skin immediately with water.

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

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. Norbrook Meloxicam 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 Norbrook Meloxicam. The treatment free period, however, should take into account the pharmacological properties of the products used previously.

Incompatibilities

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

Overdose

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 are expected to be more severe and more frequent. In the case of overdose symptomatic treatment should be initiated.

**For Animal Treatment Only.**

**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 02000/4395

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

### **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).

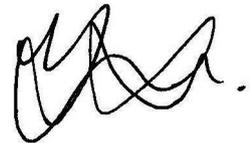
### **Package Information**

Norbrook Meloxicam 0.5 mg/ml Oral Suspension for Cats is available in 5 ml, 15 ml and 30 ml volumes.

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

### **DISTRIBUTOR**

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



Approved: 16 April 2024