PARTICULARS TO APPEAR ON THE OUTER PACKAGE

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Norbrook Meloxicam 1.5mg/ml Oral Suspension for Dogs

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:
Meloxicam 1.5 mg

3. PHARMACEUTICAL FORM

Oral Suspension.

4. PACKAGE SIZE

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

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(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

Not applicable.

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

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

16. MARKETING AUTHORISATION NUMBER

Vm 02000/4396

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
100 ml and 200 ml bottle

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Norbrook Meloxicam 1.5mg/ml Oral Suspension for Dogs

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:
Meloxicam 1.5 mg

3. PHARMACEUTICAL FORM

Oral Suspension.

4. PACKAGE SIZE

100 ml.
200 ml.

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(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

Not applicable.

9. SPECIAL WARNING(S), IF NECESSARY

Do not use in pregnant or lactating animals.

10. EXPIRY DATE

EXP:
Once opened use within 6 months.
Once opened use by: …….

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 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

16. MARKETING AUTHORISATION NUMBER

Vm 02000/4396

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 10 and 32 ml bottle

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Norbrook Meloxicam 1.5mg/ml Oral Suspension for Dogs

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Meloxicam 1.5 mg/ml

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

10 ml
32 ml

4. ROUTE(S) OF ADMINISTRATION

Oral use.
Shake well before use.

Avoid introduction of contamination during use.

5. WITHDRAWAL PERIOD

Not applicable.

6. BATCH NUMBER

BN:

7. EXPIRY DATE

EXP:
Once opened, use within 6 months.
Once opened 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 1.5mg/ml Oral Suspension for Dogs

3. STATEMENT OF THE ACTIVE SUBSTANCE (S) 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 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 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 been reported very rarely in spontaneous reports. Haemorrhagic diarrhoea, haematemesis, gastrointestinal ulceration and elevated liver enzymes have been reported very rarely in spontaneous reports.
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 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.

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 Norbrook Meloxicam 1.5mg/ml Oral Suspension for Dogs. 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.
Do not use after the expiry date stated on the carton and the bottle.
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.
This product for dogs should not be used in cats as it is not suitable for use in this species. In cats, Norbrook Meloxicom 0.5 mg/ml oral suspension for cats should be used.

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

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. 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 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 this package leaflet or the 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.

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

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

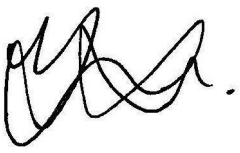
November 2023

15. OTHER INFORMATION

Vm 02000/4396

POM-V Prescription Only Medicine – Veterinarian
To be supplied only on veterinary prescription
10 ml, 32 ml, 100 ml, 2 x 100 ml, 200 ml
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 Limited
Carnbane Industrial Estate
Newry
BT35 6QQ, Co Down
Northern Ireland



Approved: 16 April 2024