

PARTICULARS TO APPEAR ON THE OUTER PACKAGE {Carton}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Meloxaid 2 mg/ml Solution for Injection for Cats

2. STATEMENT OF ACTIVE SUBSTANCES

Meloxicam 2 mg/ml

3. PACKAGE SIZE

10 ml

20 ml

4. TARGET SPECIES

Cats

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Single subcutaneous injection

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp. {mm/yyyy}

Once broached, use by:...

Once broached, use within 28 days.

9. SPECIAL STORAGE PRECAUTIONS

Keep the vial in the outer carton in order to protect from light.

10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”

Read the package leaflet before use.

User warnings

Pregnant women should not administer this product. see package leaflet for full user warnings.

11. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

C&H Generics Ltd

14. MARKETING AUTHORISATION NUMBERS

Vm 40162/3018 (NI)
Vm 40162/5018 (GB)

15. BATCH NUMBER

Lot {number}

**MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING
UNITS {VIALS}**

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Meloxaid 2 mg/ml Solution for Injection for Cats

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Meloxicam 2 mg/ml

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

Once opened use by.....

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Meloxaid 2 mg/ml Solution for Injection for Cats

2. Composition

One ml contains:

Active substance:

Meloxicam 2 mg

Excipients:

Ethanol 150 mg

Clear yellow solution.

3. Target species

Cats.

4. Indications for use

Alleviation of mild to moderate post-operative pain and inflammation following surgical procedures in cats, e.g. orthopaedic and soft tissue surgery.

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 cases of hypersensitivity to the active substance or to any of the excipients.

Do not use in cats less than 6 weeks of age nor in cats of less than 2 kg.

6. Special warnings

Special precautions for safe use in the target species:

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 cat, as there is a potential risk of renal toxicity.

During anaesthesia, monitoring and fluid therapy should be considered as standard practice.

In case additional pain relief is required, multimodal pain therapy should be considered.

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 non-steroidal anti-inflammatory drugs (NSAIDs) should avoid contact with the veterinary medicinal product.

In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.

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

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 embryofetal development, the veterinary medicinal product should not be administered by pregnant women or women attempting to conceive.

Pregnancy and lactation:

The safety of the veterinary medicinal product has not been established during pregnancy and lactation (see section 5).

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. The veterinary medicinal product must not be administered in conjunction with other NSAIDs or glucocorticosteroids. Concurrent administration of potential nephrotoxic veterinary medicinal products 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 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 pharmacological properties of the products used previously.

Overdose:

In the case of overdose symptomatic treatment should be initiated.

Special restrictions for use and special conditions for use:

Not applicable.

Major incompatibilities:

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

7. Adverse events

Cats

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Appetite loss ¹ , Lethargy ¹ Renal failure ¹ Vomiting ¹ , Diarrhoea ¹ , Blood in faeces ^{1,2} , Gastrointestinal ulceration ¹ Elevated liver enzymes ¹ Anaphylactoid reaction ³
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¹These adverse reactions are in most cases transient and disappear following termination of the treatment but in very rare cases may be serious or fatal.

²Occult.

³Should be treated symptomatically.

Reporting adverse events is important. It allows continuous safety monitoring of a product. 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 contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder or the local representative of the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system at:

Website: <https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine>

e-mail: adverse.events@vmd.gov.uk

8. Dosage for each species, routes and method of administration

Reduction of post-operative pain and inflammation 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. 0.1 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 an oral suspension veterinary medicinal product containing meloxicam authorised 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.

Reduction of post-operative pain and inflammation where no oral follow-up treatment is possible e.g. feral cats:

Single subcutaneous injection at a dosage of 0.3 mg meloxicam/kg body weight (i.e. 0.15 ml/kg body weight) before surgery, for example at the time of induction of anaesthesia. In this case do not use oral follow up treatment.

9. Advice on correct administration

Particular care should be taken with regard to the accuracy of dosing. Avoid introduction of contamination during use.

10. Withdrawal periods

Not applicable.

11. Special storage precautions

Keep out of the sight and reach of children.

Keep the vial in the outer carton in order to protect from light.

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

Do not use this veterinary medicinal product after the expiry date which is stated on the label after EXP. The expiry date refers to the last day of that month.

Shelf life after first opening the immediate packaging: 28 days

Once the vial is broached, using the shelf-life after first opening, calculate the discard date and record in the space provided on the label.

12. Special precautions for disposal

Medicines should not be disposed of via wastewater.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any applicable national collection systems. These measures should help to protect the environment.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

Vm 40162/3018 (NI)

Vm 40162/5018 (GB)

Cardboard box containing one colourless glass injection vial of 10 ml or 20 ml, closed with a bromobutyl rubber stopper and sealed with an aluminium cap.

Not all pack sizes may be marketed.

15. 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.

16. Contact details

Marketing authorisation holder,
C&H Generics Ltd
c/o Michael McEvoy and Co, Seville House
New Dock Street
Galway
H91 CKV0
Ireland

Manufacturer responsible for batch release and contact details to report suspected adverse reactions:

Chanelle Pharmaceuticals Manufacturing Ltd.,
Loughrea, Co. Galway, H62 FH90
Ireland
Telephone: +353 (0)91 841788
vetpharmacoviggroup@chanellegroup.ie

17. Other information

POM-V

Gavin Hall
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