PARTICULARS TO APPEAR ON THE OUTER PACKAGE

{Carton for 10 ml, 20 ml and 100 ml vial}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Meloxicam: 5 mg/ml,
Ethanol (96%): 159.8 mg/ml.

3. PACKAGE SIZE

10 ml
20 ml
100 ml

4. TARGET SPECIES

Dogs and cats

5. INDICATION(S)

Read the package leaflet before use.

6. 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.

Read the package leaflet before use.

7. WITHDRAWAL PERIOD(S)

8. EXPIRY DATE

EXP {month/year}
Shelf life of broached vial: 28 days.
Once broached, use by…

9. SPECIAL STORAGE PRECAUTIONS

Keep the vial in the outer carton.

10. THE WORDS "READ THE PACKAGE LEAFLET BEFORE USE"

Read the package leaflet before use.

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 AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

EU Pharmaceuticals Ltd
37 Geraldine Road
London
SW18 2NR

14. MARKETING AUTHORISATION NUMBER

GB Vm 39787/5023
NI Vm 39787/3023

15. MANUFACTURER'S BATCH NUMBER

16. SPECIAL WARNING(S), IF NECESSARY

Do not use in pregnant or lactating animals.

User warnings:
Pregnant women should not administer this product. See full user warnings for details

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

18. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE [Distribution category]

POM-V ('Veterinary medicinal product subject to prescription')

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

{Label for 100 ml vials}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Meloxaid 5 mg/ml
Meloxicam

2. STATEMENT OF ACTIVE SUBSTANCES

Meloxicam: 5 mg/ml,
Ethanol (96%): 159.8 mg/ml.

3. TARGET SPECIES

Dogs and cats

4. ROUTE OF ADMINISTRATION

Dogs: Musculo-skeletal disorders: single subcutaneous injection.
Post-operative pain: single intravenous or subcutaneous injection.

Cats: Post-operative pain: single subcutaneous injection.

5. WITHDRAWAL PERIOD(S)

6. EXPIRY DATE

EXP {month/year}
Shelf life after first opening the immediate packaging: 28 days.
Once broached, use by…

7. SPECIAL STORAGE PRECAUTIONS

Keep the vial in the outer carton.

8. NAME OF THE MARKETING AUTHORISATION HOLDER

EU Pharmaceuticals Ltd
37 Geraldine Road
London
SW18 2NR

9. BATCH NUMBER

BN {number}

10. SPECIAL WARNING(S), IF NECESSARY

Do not use in pregnant or lactating animals.

11. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF USUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Read the package leaflet before use.

12. THE WORDS 'FOR ANIMAL TREATMENT ONLY' AND CONDITIONS OF RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only.

Keep out of the sight and reach of children.

POM-V ('Veterinary medicinal product subject to prescription')

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

{Label for 10 ml and 20 ml vials}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. QUALITATIVE AND QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Meloxicam 5 mg/ml.

3. BATCH NUMBER

BN {number}

4. EXPIRY DATE

EXP {month/year}
Once broached, use by…

5. ROUTES OF ADMINISTRATION

Dogs: IV or SC.
Cats: SC.

6. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

PACKAGE LEAFLET:
Meloxaid 5 mg/ml solution for injection for dogs and cats

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. COMPOSITION

One ml contains:

Meloxicam 5 mg,
Ethanol (96%) 159.8 mg.
Clear, yellow solution.

3. TARGET SPECIES

Dogs and cats.

4. INDICATIONS FOR USE

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

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

Use during pregnancy and lactation:
Do not use in pregnant or lactating animals.
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, anti-coagulants, aminoglycoside antibiotics and substances with high protein binding may compete for binding and thus lead to toxic effects.
Meloxaid 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 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 (symptoms, emergency procedures, antidotes):
In the case of overdose, symptomatic treatment should be initiated.

7. ADVERSE REACTIONS

Dogs and cats

Rare (1 to 10 animals / 10,000 animals treated):	Digestive tract disorder: loss of appetite, vomiting, diarrhoea, blood in faeces Systematic disorder: depression Renal and urinary disorders: renal failure

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	[1]Digestive tract disorders: haemorrhagic diarrhoea, haematemesis, gastric ulceration NOS. Investigations: elevated liver enzymes. [2]Immune system disorders: anaphylactoid reactions

[1]These side effects 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.
[2]These side effects should be treated symptomatically.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See also the last section of the package leaflet for respective contact details.

National reporting system: https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

Dosage for each species:

Dogs: single administration of 0.2 mg meloxicam /kg body weight (i.e. 0.4 ml/10 kg).
Cats: single administration of 0.3 mg meloxicam/kg body weight (i.e. 0.06 ml/kg).

Method and routes of administration:

Dogs:
Musculo-skeletal disorders: single subcutaneous injection.
Meloxaid 1.5 mg/ml oral suspension for dogs or Meloxaid 1 mg and 2.5 mg chewable tablets for dogs may be used for continuation of treatment at a dosage of 0.1 mg meloxicam/kg body weight, 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 after ovariohysterectomy and minor soft tissue surgery: single subcutaneous injection before surgery, for example, at the time of induction of anaesthesia.

9. ADVICE ON CORRECT ADMINISTRATION

Particular care should be taken with regard to the accuracy of dosing.
Avoid introduction of contamination during use.
Maximum number of piercings is 42 for all presentations.

10. WITHDRAWAL PERIOD(S)

Not applicable.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the reach and sight of children.
Keep the vial in the outer carton.
Do not use after the expiry date (EXP) stated on the carton and vial.
Shelf life after first opening the container: 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

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.
Medicines should not be disposed of via wastewater.

13. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCT

Veterinary medicinal product subject to prescription (POM-V)

14. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

GB Vm 39787/5023
NI Vm 39787/3023

Carton box containing one colourless glass injection vial of 10 ml, 20 ml or 100ml, 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:
EU Pharmaceuticals Ltd
37 Geraldine Road
London, SW18 2NR

Manufacturer responsible for batch release:
Chanelle Pharmaceuticals Manufacturing Ltd.,
Loughrea, Co. Galway,
Ireland

and

Eurovet Animal Health B.V.
Handelsweg 25, 5531 AE Bladel,
The Netherlands

and

Labiana Life Sciences, S.A.,
C/ Venus, 26, Pol. Ind. Can Parellada, Tarrasa,
08228 Barcelona

Local representatives and contact details to report suspected adverse reactions:

CVS (UK) Limited
CVS House, Owen
Road, Diss, Norfolk
IP22 4ER United
Kingdom

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

17. OTHER INFORMATION

For animal treatment only.

Gavin Hall

Approved: 18 November 2024