PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Cardboard box of 5 ml vial
Cardboard box of 15 ml vial

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Meloxicam Ceva 0.5 mg/ml oral suspension.

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

0.5 mg/ml of meloxicam.
2.0 mg/ml Sodium benzoate (E 211)

3. PACKAGE SIZE

Cardboard box of 5 ml vial
Cardboard box of 15 ml vial

4. TARGET SPECIES

Cats

5. INDICATION(S)

6. ROUTES OF ADMINISTRATION

Oral use.

7. WITHDRAWAL PERIODS

Exp:
Once opened, use within 6 months.

8. EXPIRY DATE

9. SPECIAL STORAGE PRECAUTIONS

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 OF THE MARKETING AUTHORISATION HOLDER

14. MARKETING AUTHORISATION NUMBERS

Vm 15052/3022

15. BATCH NUMBER

Lot:

16. SPECIAL WARNING(S), IF NECESSARY

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

Disposal: read package leaflet

18. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

POM-V – Veterinary medicinal product subject to prescription

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Label of 5 ml
Label of 15 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Meloxicam Ceva

2. QUALITATIVE AND QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

0.5 mg/ml of meloxicam.
2.0 mg/ml Sodium benzoate (E 211)

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}
Once opened use within 6 months.

5. ROUTE(S) OF ADMINISTRATION

Oral use.

6. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Meloxicam Ceva 0.5 mg/ml oral suspension for cats

2. COMPOSITION

Each ml contains:

Active substance: Meloxicam 0.5 mg

Excipient: Sodium benzoate (E211) 2 mg

Pale yellow suspension

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.

Alleviation of pain and inflammation in acute and chronic musculo-skeletal disorders in cats.

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 known cases of hypersensitivity to the active substance or to any of the excipients. Do not use in cats less than 6 weeks of age.

6. SPECIAL WARNINGS

Special warnings:

None.

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 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.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:

Meloxicam and other non-steroidal anti-inflammatory drugs (NSAIDs) may cause hypersensitivity (allergic reactions).

People with known hypersensitivity to NSAIDs should avoid contact with the veterinary medicinal product.

Accidental ingestion of the product by a child may cause gastro-intestinal effects, such as nausea and gastric pain.

Any uneaten medicated food must be disposed of immediately and the bowl washed thoroughly.

Do not leave an unattended filled syringe in the sight or reach of children.

In case of accidental ingestion, 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.

Wash hands after use.

Special precautions for the protection of the environment:

Not applicable.

Pregnancy and lactation:

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

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

Overdose:

Meloxicam has a narrow therapeutic safety margin in cats and clinical signs of overdose may be seen at relatively small overdose levels.

In case of overdose, adverse reactions, as listed in section “Adverse events” are expected to be more severe and more frequent. In the case of overdose symptomatic treatment should be initiated.

Major incompatibilities:

None known.

Special precautions for the protection of the environment:

Not applicable.

7. ADVERSE EVENTS

Cats:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Vomiting[1], Diarrhoea[1], Blood in faeces[1], Gastic ulceration[1] Appetite loss[1], Apathy[1]Renal failure[1] Elevated liver enzymes[1]

[1]These side effects disappear following termination of the treatment but in very rare cases may be serious or fatal.

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.
National contact details: https://www.gov.uk/report-veterinary-medicine-problem

8. DOSAGE FOR EACH SPECIES, ROUTES AND METHOD OF ADMINISTRATION

Post-operative pain and inflammation following surgical procedures:

After initial treatment with meloxicam 2 mg/ml solution for injection for cats, continue treatment 24 hours later with the veterinary medicinal product at a dosage of

0.05 mg meloxicam/kg bodyweight. 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

Shake well before use. To be administered orally either mixed with food or directly into the mouth.

The suspension can be given using the measuring syringe provided in the package.

The syringe fits onto the bottle and has a kg-body weight scale (from 1 kg to 10 kg) which corresponds to the maintenance dose (i.e. 0.05 mg meloxicam/kg body weight). Thus for initiation of the therapy on the first day, twice the maintenance volume will be required.

Avoid introduction of contamination during use.

9. ADVICE ON CORRECT ADMINISTRATION

Particular care should be taken with regard to the accuracy of dosing. The recommended dose should not be exceeded.

Please carefully follow the instructions of the veterinarian.

10. WITHDRAWAL PERIODS

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. Shelf life after first opening the container: 6 months.

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

12. SPECIAL PRECAUTIONS FOR DISPOSAL

Medicines should not be disposed of via wastewater.

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements. Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

These measures should help to protect the environment.

13. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

14. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

Vm 15052/3022

Pack sizes

Cardboard box containing 15 ml high density polyethylene bottle with one measuring syringe.

Cardboard box containing 5 ml glass bottle with one measuring syringe.

The measuring syringe has a kg-body weight scale for cats (1 to 10 kg).

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 and contact details to report suspected adverse reactions:
Ceva Animal Health Ltd
Explorer House, Mercury Park, Wycombe Lane Wooburn Green, High Wycombe, Buckinghamshire HP10 0HH
United Kingdom

Manufacturer responsible for batch release:
Ceva Santé Animale
10 av. de La Ballastière
33500 Libourne
FRANCE

17. OTHER INFORMATION

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

For animal treatment only.

Gavin Hall

Approved: 12 June 2024