# PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Cardboard box of 10 ml vial

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Meloxicam Ceva 5 mg/ml solution for injection.

## 2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

5 mg/ml meloxicam.

## 3. PACKAGE SIZE

Cardboard box of 10 ml vial

## 4. TARGET SPECIES

Dogs and cats.

## 5. INDICATION(S)

## 6. ROUTES OF ADMINISTRATION

Dogs: intravenous or subcutaneous use
Cats: subcutaneous use

## 7. WITHDRAWAL PERIODS

## 8. EXPIRY DATE

Exp:
Once broached, use by:

## 9. SPECIAL STORAGE PRECAUTIONS

Do not store above 25° C.

## 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 15052/5061

## 15. BATCH NUMBER

Lot:

## 16. SPECIAL WARNING(S), IF NECESSARY

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

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 10 ml

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Meloxicam Ceva

## 2. QUALITATIVE AND QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

## 3. BATCH NUMBER

Lot {number}

## 4. EXPIRY DATE

Exp. {mm/yyyy}
Once broached, use by

## 5. ROUTE(S) OF ADMINISTRATION

Dogs: intravenous or subcutaneous use
Cats: subcutaneous 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 5 mg/ml solution for injection for dogs, cats

## 2. COMPOSITION

One ml contains:

**Active substance:**

Meloxicam: 5 mg.

**Excipients:**

Ethanol anhydrous: 150 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 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 known cases 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 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 increased renal toxicity.
Any oral follow-up therapy using meloxicam or other non-steroidal anti-inflammatory drugs (NSAIDs) should not be administered in cats, as appropriate dosage regimens for such follow-up treatments have not been established.

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 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.

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 veterinary medicinal product 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 drugs 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:
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

Dogs:

| | |
|---|---|
| Very rare (<1 animal / 10,000 animals treated, including isolated reports): | Anaphylactoid reaction, Vomiting[1], Diarrhoea[1], Blood in faeces[1], Appetite loss[1], Apathy[1], Renal failure[1] |

Cats:

| | |
|---|---|
| Very rare (<1 animal / 10,000 animals treated, including isolated reports): | Anaphylactoid reaction, Vomiting[1], Diarrhoea[1], Faecal occult blood[1] Appetite loss[1], Apathy[1] Renal failure[1] |

[1]These side effects occur within the first treatment week. They 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

**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 route of administration**
Dogs:
Musculo-skeletal disorders: single subcutaneous injection.
Meloxicam Ceva 1.5 mg/ml oral suspension 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.
Avoid introduction of contamination during use.

## 9. ADVICE ON CORRECT ADMINISTRATION

Particular care should be taken with regard to the accuracy of dosing.

## 10. WITHDRAWAL PERIODS

Not applicable.

## 11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

Do not store above 25°C.
Shelf life after first opening the container: 28 days.
Do not use this veterinary medicinal product after the expiry date which is stated on the cardboard box and the vial after Exp. The expiry date refers to the last day of that month.

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.

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 15052/5061

Pack size:
10 ml bottle in a cardboard box

## 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

*Gavin Hall*

Approved: 12 June 2024