PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Cardboard box of 10 ml vial
Cardboard box of 32 ml vial
Cardboard box of 100 ml vial

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Meloxicam Ceva 1.5 mg/ml oral suspension.

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

1.5 mg/ml of meloxicam.
2.0 mg/ml Sodium benzoate

3. PACKAGE SIZE

Cardboard box of 10 ml vial
Cardboard box of 32 ml vial
Cardboard box of 100 ml vial

4. TARGET SPECIES

Dogs.

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 15052/5057

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

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

Label of 100ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Meloxicam Ceva 1.5 mg/ml oral suspension.

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

1.5 mg/ml of meloxicam.
2.0 mg/ml Sodium benzoate

3. TARGET SPECIES

Dogs.

4. ROUTES OF ADMINISTRATION

Oral use.

5. WITHDRAWAL PERIODS

6. EXPIRY DATE

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

7. SPECIAL STORAGE PRECAUTIONS

8. NAME OF THE MARKETING AUTHORISATION HOLDER

9. BATCH NUMBER

Lot {number}

10. SPECIAL WARNING(S), IF NECESSARY

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

Disposal: read package leaflet

12. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE

For animal treatment only.

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

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Label of 10 ml
Label of 32 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Meloxicam Ceva

2. QUALITATIVE AND QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

1.5 mg/ml of meloxicam.
2.0 mg/ml Sodium benzoate

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 1.5 mg/ml oral suspension for dogs.

2. COMPOSITION

Each ml contains:

Active substance: Meloxicam 0.5 mg

Excipient: Sodium benzoate (E211) 2 mg

Pale yellow suspension

3. TARGET SPECIES

Dogs.

4. INDICATIONS FOR USE

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

6. SPECIAL WARNINGS

Special warnings:
None.

Special precautions for safe use in the target species:
If side effects occur, treatment should be discontinued and the advice of a veterinarian should be sought. Avoid use in any dehydrated, hypovolaemic or hypotensive animal, if there is a potential risk of increased renal toxicity.

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.

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.
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 veterinary medicinal products used previously.

Overdose:
In the case of overdosage, seek medical advice.

Major incompatibilities:
Not applicable.

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):	Vomiting[1], Diarrhoea[1], Blood in faeces[1], Gastric ulceration[1], Haemorrhagic diarrhoea1, Haematemesis1 Appetite loss[1], Apathy[1] Elevated liver enzymes[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

Oral use.
Shake well before use. To be administered mixed with food.
Initial treatment is a single 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 maintenance dose of 0.1 mg meloxicam/kg body weight.

For longer term treatment, once a 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.

The suspension can be given using the measuring syringes provided in the package. The syringe fits onto the bottle and has a kg-body weight scale which corresponds to the maintenance dose (i.e. 0.1mg Meloxicam/kg body weight). Thus, for the first day, twice the maintenance volume will be required.

Dosing procedure using the measuring syringe:

Shake bottle well. Push down and unscrew bottle top.	Attach the dosing syringe to the bottle by gently pushing the end onto the top of the bottle.	Turn the bottle and syringe upside down. Withdraw the plunger until the black line on the plunger corresponds to your dog's bodyweight in kilograms.	Return the bottle and syringe upright and remove the syringe.	Depress the plunger to empty the contents of the syringe onto the food.

A clinical response is normally seen within 3-4 days. Treatment should be discontinued after 10 days after the latest if no clinical improvement is apparent.

To avoid introduction of external contaminants during use, do not remove the bottle insert and keep the provided syringes only for this product.

9. ADVICE ON CORRECT ADMINISTRATION

Particular care should be taken with regard to the accuracy of dosing.
The suspension could be administered using the smallest syringe for dogs less than 7 kg body weight (one graduation corresponding to 0.5 kg of body weight) or the largest syringe for dogs over than 7 kg body weight (one graduation corresponding to 2.5 kg of body weight).

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 15052/5057

Pack sizes
Two measuring syringes are provided per each presentation.
10 ml bottle in a cardboard box
32 ml bottle in a cardboard box
100 ml bottle in a cardboard box
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

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