PARTICULARS TO APPEAR ON THE OUTER PACKAGE {Cardboard box}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Meloxoral 1.5 mg/ml oral suspension

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each ml contains: Meloxicam 1.5 mg.

3. PACKAGE SIZE

10 ml
25 ml
50 ml
125 ml
180 ml

4. TARGET SPECIES

Dogs

5. INDICATION(S)

6. ROUTES OF ADMINISTRATION

Oral use.
Shake well before use.

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp. {month/year}
Once opened, use within 6 months.
Once broached, use by…

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

Dechra Regulatory B.V.

14. MARKETING AUTHORISATION NUMBERS

Vm 50406/5001

15. BATCH NUMBER

Lot {number}

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

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE { Bottle of 125 or 180 ml}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Meloxoral 1.5 mg/ml oral suspension

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each ml contains: Meloxicam 1.5 mg.

3. TARGET SPECIES

Dogs

4. ROUTES OF ADMINISTRATION

Shake well before use.
Oral use.
Read the package leaflet before use.

5. WITHDRAWAL PERIODS

6. EXPIRY DATE

EXP {month/year}
Once opened, use within 6 months.
Once broached, use by…

7. SPECIAL STORAGE PRECAUTIONS

8. NAME OF THE MARKETING AUTHORISATION HOLDER

Dechra Regulatory B.V.

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

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

For animal treatment only.

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS {Bottle of 10, 25 or 50 ml}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Meloxoral

2. QUALITATIVE AND QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Meloxicam 1.5 mg/ml

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {month/year}
Once opened, use within 6 months.
Once broached, use by…

5. ROUTE(S) OF ADMINISTRATION

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

Meloxoral 1.5 mg/ml oral suspension for dogs

2. COMPOSITION

Each ml contains:

Active substance:
Meloxicam 1.5 mg.

Excipient:
Sodium benzoate 1.75 mg.

Yellow/ green 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 dogs 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 dogs less than 6 weeks of age.

6. SPECIAL WARNING(S)

Special precautions for use in animals:
Avoid use in any dehydrated, hypovolaemic or hypotensive animal, as there is a potential risk of increased renal toxicity.

This product for dogs should not be used in cats as it is not suitable for use in this species. In cats, Meloxoral 0.5 mg/ml oral suspension for cats should be used.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
People with known hypersensitivity to non-steroidal anti-inflammatory drugs (NSAIDs) should avoid contact with the veterinary medicinal product.

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

Pregnancy and lactation:
The safety of the veterinary medicinal product has not been established during pregnancy and lactation.

Do not use in pregnant or lactating animals.

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. Meloxoral 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 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 case of overdose symptomatic treatment should be initiated.

7. ADVERSE EVENTS

Dogs:

Very Rare (<1 animal / 10,000 treated, including isolated reports):	Appetite loss[1], Apathy[1] Vomiting[1], Diarrhoea[1], Blood in faeces[1,2], Haemorrhagic diarrhoea[1], Haematemesis[1], Gastric ulcer[1], Small intestine ulcer[1], Large intestine ulcer[1] Renal failure[1] Elevated liver enzymes[1]

[1] These reactions 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. If adverse reactions occur, treatment should be discontinued and the advice of a veterinarian should be sought.
[2] occult

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 inform your veterinary surgeon.

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 using the contact details at the end of this leaflet, or via your national reporting system:
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

Oral use.
To be administered either mixed with food or directly into the mouth.

Dosage
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 clinical response has been observed (after ≥ 4 days), the dose of Meloxoral 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.

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

9. ADVICE ON CORRECT ADMINISTRATION

Shake well before use.

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

The syringe fits onto the drop dispenser of the bottle and has a kg-body weight scale which corresponds to the maintenance dose. Thus for initiation of the therapy on the first day, twice the maintenance volume will be required.

After each dose, the tip of the syringe should be wiped and the bottle cap screwed back on tightly. The syringe should be stored in the carton box in between uses.
To avoid introduction of external contaminants during use, keep the provided syringes only for this product.

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

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.
Shelf life after first opening the immediate packaging: 6 months.

12. SPECIAL PRECAUTIONS FOR DISPOSAL

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

Medicines should not be disposed of via wastewater.

13. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

14. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

Vm 50406/5001

Cardboard box with 1 bottle of 10 ml, 25 ml, 50 ml, 125 ml or 180 ml and a measuring syringe.
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:

Dechra Regulatory B.V.
Handelsweg 25
5531 AE Bladel
The Netherlands
+44 (0) 1939 211200

Manufacturer responsible for batch release:

Genera Inc.Kalinovica,
Svetonedeljska cesta 2
10436 Rakov Potok
Croatia

Produlab Pharma BV
Forellenweg 16
4941 SJ Raamsdonksveer
The Netherlands

17. OTHER INFORMATION

POM-V

Gavin Hall
Approved: 06 July 2024