PARTICULARS TO APPEAR ON THE OUTER PACKAGE

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

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. STATEMENT OF ACTIVE SUBSTANCES

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

3. PHARMACEUTICAL FORM

Solution for injection

4. PACKAGE SIZE

10 ml
20 ml
100 ml

5. TARGET SPECIES

Dogs and cats

6. INDICATION(S)

Read the package leaflet before use.

7. METHOD AND 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.

8. WITHDRAWAL PERIOD(S)

9. SPECIAL WARNING(S), IF NECESSARY

Do not use in pregnant or lactating animals.

10. EXPIRY DATE

EXP {month/year}
Shelf life of broached vial: 28 days.

11. SPECIAL STORAGE CONDITIONS

Keep the vial in the outer carton.

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Read the package leaflet before use.

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

For animal treatment only. To be supplied only on veterinary prescription.

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Chanelle Pharmaceuticals Manufacturing Ltd.,
Loughrea,
Co. Galway,
Ireland.

16. MARKETING AUTHORISATION NUMBER

Vm 08749/5024

17. MANUFACTURER'S BATCH NUMBER

BN {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

{Label for 100 ml vials}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. STATEMENT OF ACTIVE SUBSTANCES

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

3. PHARMACEUTICAL FORM

Solution for injection.

4. PACKAGE SIZE

100 ml

5. TARGET SPECIES

Dogs and cats

6. INDICATIONS

Read package leaflet before use.

7. METHOD AND 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.

8. WITHDRAWAL PERIOD(S)

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

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

11. SPECIAL STORAGE CONDITIONS

Keep the vial in the outer carton.

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

Read the package leaflet before use.

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

For animal treatment only. To be supplied only on veterinary prescription.

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Chanelle Pharmaceuticals Manufacturing Ltd
Loughrea
Co. Galway
Ireland

16. MARKETING AUTHORISATION NUMBER

Vm 08749/5024

17. MANUFACTURER'S BATCH NUMBER

BN {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

{Label for 10 ml and 20 ml vials}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Meloxicam 5 mg/ml.

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

10 ml
20 ml

4. ROUTES OF ADMINISTRATION

Dogs: IV or SC.
Cats: SC.

5. WITHDRAWAL PERIOD(S)

6. BATCH NUMBER

BN {number}

7. EXPIRY DATE

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

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

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

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder:
Chanelle Pharmaceuticals Manufacturing Ltd.,
Loughrea, Co. Galway,
Ireland

Manufacturers responsible for the 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

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

One ml contains:

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

4. INDICATIONS

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. ADVERSE REACTIONS

Typical adverse reactions of non-steroidal anti-inflammatory drugs (NSAIDs) such as loss of appetite, vomiting, diarrhoea, faecal occult blood, apathy and renal failure, have occasionally been reported. In very rare cases elevated liver enzymes have been reported.

In very rare cases, haemorrhagic diarrhoea, haematemesis, and gastrointestinal ulceration have been reported.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.
In very rare cases, anaphylactoid reactions may occur and should be treated symptomatically.
If adverse reactions occur, treatment should be discontinued and the advice of a veterinarian should be sought.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reactions)
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

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.

7. TARGET SPECIES

Dogs and cats.

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.
Rheumocam 1.5 mg/ml oral suspension for dogs or Rheumocam 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.

12. 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.
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 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.

Use 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, anti-coagulants, aminoglycoside antibiotics and substances with high protein binding may compete for binding and thus lead to toxic effects. Rheumocam 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.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIAL, IF ANY

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

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

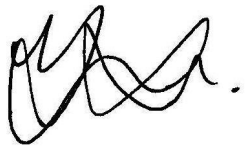
26/10/2020

15. OTHER INFORMATION

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.

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

United Kingdom
Chanelle Vet UK Ltd
Freemans House
127 High Street
Hungerford
RG17 0DL
UK



Approved: 11 June 2021