Rheumocam 1.5 mg/ml oral suspension for dogs

STATEMENT OF THE ACTIVE SUBSTANCE
Meloxicam 1.5 mg/ml.

MANUFACTURER
Chanelle Pharmaceuticals Manufacturing Ltd., Loughrea, Co. Galway, Ireland.
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NAME OF THE VETERINARY MEDICINALPRODUCT
Rheumocam 1.5 mg/ml oral suspension for dogs.
A yellow coloured suspension.

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

PHARMACODYNAMICS
Meloxicam is a non-steroidal anti-inflammatory drug (NSAID) of the oxicam class which acts by inhibition of prostaglandin synthesis, thereby exerting anti-inflammatory, analgesic, anti-exudative and antipyretic effects. It reduces leukocyte infiltration into the inflamed tissue. To a minor extent it also inhibits collagen-induced thrombocyte aggregation. *In vitro* and *in vivo* studies demonstrated that meloxicam inhibits cyclooxygenase-2 (COX-2) to a greater extent than cyclooxygenase-1 (COX-1).

PHARMACOKINETICS

Absorption
Meloxicam is completely absorbed following oral administration and maximal plasma concentrations are obtained after approximately 7.5 hours. When the product is used according to the recommended dosage regime, steady state concentrations of meloxicam in plasma are reached on the second day of treatment.

Distribution
There is a linear relationship between the dose administered and plasma concentration observed in the therapeutic dose range. Approximately 97% of meloxicam is bound to plasma proteins. The volume of distribution is 0.3 l/kg.

Metabolism
Meloxicam is predominantly found in plasma and is also a major biliary excretion product whereas urine contains only traces of the parent compound. Meloxicam is metabolised to an alcohol, an acid derivative and to several polar metabolites. All major metabolites have been shown to be pharmacologically inactive.

Elimination
Meloxicam is eliminated with a half-life of 24 hours. Approximately 75% of the administered dose is eliminated via faeces and the remainder via urine.

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

ADVERSE REACTIONS
Typical adverse reactions of NSAIDs such as loss of appetite, vomiting, diarrhoea, faecal occult blood and apathy have occasionally 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.

If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

TARGET SPECIES
Dogs.

DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION
Shake well before use.
To be administered mixed with food.
Avoid introduction of contamination during use.
Initial treatment is a single dose of 0.2mg 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.
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 which corresponds to the maintenance dose (i.e. 0.1 mg meloxicam/kg body weight).
The following dosing table indicates the volume to be administered depending on the weight of the dog:

Bodyweight	Maintenance Dosage	Bodyweight	Maintenance Dosage
7.5 kg	0.5 ml	37.5 kg	2.5 ml
15kg	1 ml	45 kg	3 ml
22.5 kg	1.5 ml	52.5 kg	3.5 ml
30 kg	2 ml	60 kg	4 ml

For the first day, twice the maintenance volume will be required.
A clinical response is normally seen within 3 to 4 days. Treatment should be discontinued after 10 days at the latest if no clinical improvement is apparent.

Please follow these steps:

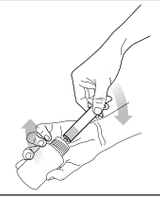
Step 1.
Before using Rheumocam for the very first time ensure that you have the bottle, circular plastic insert and syringe.

Step 2.
Place the circular plastic insert into the neck of the bottle and push down until securely in place. Once in place the insert will not need to be removed.

Step 3.
Replace the cap onto the bottle and shake it well. Take off the bottle cap and attach the dosing syringe to the bottle by gently pushing the end into the hole.

Step 4.
Tum the bottle with the syringe in place upside down and slowly withdraw the plunger until the required dose is evident.

Step 5 .
Turn the bottle/syringe the right way up and with a twisting movement separate the syringe from the bottle.



Step 6.
Push the plunger until all contents of the syringe have been dispensed onto the food.

ADVICE ON CORRECT ADMINISTRATION
Particular care should be taken with regard to the accuracy of dosing. Please carefully follow the instructions of the veterinarian.

WITHDRAWAL PERIOD
Not applicable.

SPECIAL STORAGE PRECAUTIONS
Store below 25ºC.
Keep out of the reach and sight of children.
Do not use after the expiry date (EXP) stated on the bottle.

SPECIAL WARNING(S)
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, as there is a potential risk of increased renal toxicity.

Other NSAIDs, diuretics, anticoagulants, 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 glucocorticosteriods.

Pre-treatment with anti-inflammatory substances may result in additional or increased adverse effects and accordingly a treatment-free period with such veterinary products 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 products used previously.

In the case of overdosage symptomatic treatment should be initiated.

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

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

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

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 products should be disposed of in accordance with local requirements.

DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

OTHER INFORMATION
For animal treatment only.

42, 100 or 200 ml bottle with a measuring syringe.
Not all pack sizes may be marketed.

Manufactured by:
Chanelle Pharmaceuticals Manufacturing Ltd.,
Loughrea, Co. Galway, Ireland.

Registration holder:
RHONE MA MALAYSIA SDN BHD (200001023279)
Lot 18A & 18B, Jalan 241, Seksyen 51A,
46100 Petaling Jaya, Selangor, Malaysia.

5LRHEUM3-042 02/XXX

LABEL CODE:	VERSION	COLORS
5LRHEUM3-042 **PRODUCT:** RHEUMOCAM 1.5 MG/ML ORAL SUSPENSION **PACK SIZE:** 42 ML **COUNTRY:** MY **DIMENSIONS:** **cm =** 15.6 x 25.8	**Version:** 2 **MMM/YY:** XX	Black Please use the official PANTONE® (P) matching system for an accurate color representation.

Marketing approval:	**Regulatory** approval:
COMPLETE NAME: **DATE +** **SIGNATURE:**	**COMPLETE NAME:** **DATE +** **SIGNATURE:**