1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Rheumocam 1 mg chewable tablets for dogs
Rheumocam 2.5 mg chewable tablets for dogs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each chewable tablet contains:

Active substance:

Meloxicam 1 mg
Meloxicam 2.5 mg

Excipients:

Qualitative composition of excipients and other constituents
Lactose monohydrate
Silicified microcrystalline cellulose
Sodium acid citrate
Crospovidone
Talc
Pork flavour
Magnesium stearate

Pale-yellow, single-scored, chewable tablets that can be divided into equal halves.

3. CLINICAL INFORMATION

3.1 Target species

Dogs.

3.2 Indications for use for each target species

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

3.3 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 dogs less than 6 weeks of age or less than 4 kg body weight.
Do not use in case of hypersensitivity to the active substance or to any of the excipients.

3.4 Special warnings

None.

3.5 Special precautions for use

Special precautions for safe use in the target species:

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

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

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Dogs:

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

[1]occult

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 adverse reactions occur, treatment should be discontinued and the advice of a veterinarian should be sought.

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. See also the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

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

3.8 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 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 pharmacokinetic properties of the veterinary medicinal products used previously.

3.9 Administration routes and dosage

Oral use.

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.

Each chewable tablet contains either 1 mg or 2.5 mg meloxicam, which corresponds to the daily maintenance dose for a 10 kg body weight dog, or a 25 kg body weight dog, respectively.

Each chewable tablet can be halved for accurate dosing according to the individual body weight of the animal.

To ensure a correct dosage, body weight should be determined as accurately as possible. The use of suitably calibrated measuring equipment is recommended.

These chewable tablets can be administered with or without food, are flavoured and are taken by most dogs voluntarily.

Dose scheme for the maintenance dose:

Body weight (kg)	Number of chewable tablets		mg/kg
	1 mg	2.5 mg	
4.0–7.0	½		0.13–0.1
7.1–10.0	1		0.14–0.1
10.1–15.0	1½		0.15–0.1
15.1–20.0	2		0.13–0.1
20.1–25.0		1	0.12–0.1
25.1–35.0		1½	0.15–0.1
35.1–50.0		2	0.14–0.1

The use of Rheumocam oral suspension for dogs may be considered for an even more precise dosing. For dogs weighing less than 4 kg the use of Rheumocam oral suspension for dogs is recommended.

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

3.10 Symptoms of overdose (and where applicable, emergency procedures, antidotes)

In case of overdose, symptomatic treatment should be initiated.

3.11 Withdrawal periods

Not applicable.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QMO1AC06.

4.2 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-l (COX-I).

4.3 Pharmacokinetics

Absorption
Meloxicam is completely absorbed following oral administration and maximal plasma concentrations are obtained after approximately 4.5 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.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

None known.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 5 years.

5.3 Special precautions for storage

This veterinary medicinal product does not require any special storage precautions.

5.4 Nature and composition of immediate packaging

PVC/PVDC blister packs with a 20 micron foil.
Pack sizes: 20 and 100 chewable tablets.
Not all pack sizes may be marketed.

5.5 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products

Medicines should not be disposed of via wastewater or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Chanelle Pharmaceuticals Manufacturing Ltd.

7. MARKETING AUTHORISATION NUMBER(S)

EU/2/07/078/005 1 mg 20 tablets
EU/2/07/078/006 1 mg 100 tablets
EU/2/07/078/007 2.5 mg 20 tablets
EU/2/07/078/008 2.5 mg 100 tablets

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: 10/01/2008.

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

{DD/MM/YYYY}

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).