

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Lemicam 2.5 mg chewable tablets for dogs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

One chewable tablet contains:

Active substance:

Meloxicam 2.5 mg

Excipients:

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Chewable tablets.

Light brown to brown coloured round mottled biconvex tablet debossed with "F and 6" on either side of breakline on one side and "M2" on other side.

The tablet can be divided into halves.

4. CLINICAL PARTICULARS

4.1 Target species

Dogs

4.2 Indications for use, specifying the target species

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

4.3 Contraindications

Do not use in pregnant or lactating animals.

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 dogs less than 6 weeks of age or less than 4 kg body weight.

Do not use in cases of hypersensitivity to the active substance or to any of the excipients.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

Special precautions for use in animals

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

This product for dogs should not be used in cats as it is not suitable for use in this species. In cats, Meloxicam 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 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.

Return part-used tablets into the blister and carton.

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

4.6 Adverse reactions (frequency and seriousness)

Typical adverse reactions of NSAIDs such as loss of appetite, vomiting, diarrhoea, faecal occult blood, lethargy and renal failure have very rarely been reported from post-marketing safety experience.

Very rare cases of haemorrhagic diarrhoea, haematemesis, gastrointestinal ulceration and elevated liver enzymes have been reported from post-marketing safety experience.

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.

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).

4.7 Use during pregnancy, lactation or lay

The safety of the veterinary medicinal product has not been established during pregnancy and lactation (see section 4.3).

4.8 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. Meloxicam 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.

4.9 Amounts to be administered and administration route

Initial treatment is a single dose of 0.2 mg meloxicam/kg body weight on the first day, which can be given orally or alternatively using Meloxicam 5 mg/ml solution for injection for dogs and cats.

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 2.5 mg meloxicam, which corresponds to the daily maintenance dose for a 25 kg body weight dog respectively.

Each chewable tablet can be halved for accurate dosing according to the individual body weight of the dog. Meloxicam 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 Meloxicam oral suspension for dogs may be considered for an even more precise dosing. For dogs weighing less than 4 kg the use of Meloxicam 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.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

In case of overdose symptomatic treatment should be initiated.

4.11 Withdrawal period(s)

Not applicable.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Anti-inflammatory and antirheumatic products, non-steroids (oxicams). ATCvet code: QM01AC06.

5.1 Pharmacodynamic properties

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).

5.2 Pharmacokinetic particulars

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 in faeces and the remainder in urine.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Cellulose, microcrystalline (PH 101)
Sodium citrate
Pregelatinized Maize Starch
Iron oxide brown
Iron oxide yellow
Artificial Powdered Flavour
Cellulose, microcrystalline (PH 102)
Silica, colloidal anhydrous
Magnesium stearate
Purified Water

6.2 Major incompatibilities

None known.

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years.

6.4 Special precautions for storage

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

Unused tablet halves should be stored in the blister and given at the next administration.

6.5 Nature and composition of immediate packaging

Cardboard boxes containing 7, 84 or 252 tablets in Alu/Alu blisters. Not all pack sizes may be marketed.

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

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

7. MARKETING AUTHORISATION HOLDER

Felix Pharmaceuticals PVT Limited
25-28 North Wall Quay
Dublin 1
D01H104
Ireland

8. MARKETING AUTHORISATION NUMBER

Vm 53540/5001

9. DATE OF FIRST AUTHORISATION

24 August 2022

10. DATE OF REVISION OF THE TEXT

August 2022

Approved 24 August 2022

A handwritten signature in black ink, appearing to read 'M. M. M.', located below the approval date.