SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Metaxx 0.25 mg chewable tablets for cats

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains:

Active substance:
Meloxicam 0.25 mg

Excipients:

Qualitative composition of excipients and other constituents
Sodium citrate
Cellulose, microcrystalline
Lactose monohydrate
Crospovidone
Silica, colloidal hydrated
Chicken flavour
Yeast (dried)
Magnesium stearate

Chewable tablet
Light brown, slightly dotted, circular, biconvex, 7 mm tablet with a cross-shaped break line on one side.
The tablets can be divided into two or four equal parts.

3. CLINICAL INFORMATION

3.1 Target species

Cats

3.2 Indications for use for each target species

Alleviation of mild to moderate post-operative pain and inflammation following surgical procedures, e.g. orthopaedic and soft tissue surgery.
Alleviation of pain and inflammation in acute and chronic musculo-skeletal disorders.

3.3 Contraindications

Do not use in pregnant or lactating cats.
Do not use in cats suffering from gastrointestinal disorders such as irritation and haemorrhage, impaired hepatic, cardiac or renal function and haemorrhagic disorders.
Do not use in cases of hypersensitivity to the active substance or to any of the excipients.
Do not use in cats less than 6 weeks of age or weighing less than 1.25 kg.

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 cat, as there is a potential risk of renal toxicity.
As the chewable tablets are flavoured, store tablets out of reach of cats to avoid accidental ingestion.

Post-operative use:
In case additional pain relief is required, multimodal pain therapy should be considered.

Chronic musculoskeletal disorders:
Response to long-term therapy should be monitored at regular intervals by a veterinary surgeon.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
Meloxicam and other non-steroidal anti-inflammatory drugs (NSAIDs) may cause hypersensitivity reactions. People with known hypersensitivity to NSAIDs should avoid contact with the veterinary medicinal product. Wash hands after use.

Accidental ingestion by children may be harmful. Unused tablet parts should therefore be returned into the blister and carton and stored in a safe place. Part used tablets should be used at the time of the next dose. In case of accidental ingestion by a child 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

Cats:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Appetite loss, vomiting, diarrhoea, blood in faeces*. Lethargy*. Renal failure *. Gastrointestinal ulceration. Elevated liver enzymes.

* Typical adverse reactions of NSAIDs

These side effects 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 the national competent authority via the national reporting system. See section “Contact details” of the package leaflet.

3.7 Use during pregnancy, lactation or lay

The safety of the veterinary medicinal product has not been established during pregnancy and lactation (See section 3.3).

3.8 Interaction with other medicinal products and other forms of interaction

Other NSAIDs, diuretics, anticoagulant, 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. Concurrent administration of potential nephrotoxic drugs should be avoided.

Pre-treatment with anti-inflammatory substances other than meloxicam at a single dose of 0.2 mg/kg 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.

3.9 Administration routes and dosage

Oral use.

<u>Post-operative pain and inflammation following surgical procedures:</u>
After initial treatment with a suitable injectable formulation of meloxicam authorised for cats, continue treatment 24 hours later at a dosage of 0.05 mg meloxicam/kg

body weight. The oral follow-up dose may be administered once daily (at 24-hour intervals) for up to four days.

Acute musculo-skeletal disorders:
Initial treatment is a single oral 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 dose of 0.05 mg meloxicam/kg body weight for as long as acute pain and inflammation persist.

Chronic musculo-skeletal disorders:
Initial treatment is a single oral dose of 0.1 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 0.05 mg meloxicam/kg body weight. A clinical response is normally seen within 7 days. Treatment should be discontinued after 14 days at the latest if no clinical improvement is apparent.

Dosing table for maintenance dose of 0.05 mg/kg:

Weight (kg)	**tablet**	
1.25 – 2.2		¼ tablet
2.3 – 3.4		½ tablet
3.5– 4.5		¾ tablet
4.6 – 5.7		1 tablet
5.8 - 7		1 ¼ tablet

The recommended dose should not be exceeded.
The tablets can be administered with or without food.

Chewable tablets can be divided into two or four equal parts, for dosage accuracy, according to the bodyweight.

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

Meloxicam has a narrow therapeutic safety margin and clinical signs of overdose may be seen at relatively small overdose levels.
In case of overdose, adverse reactions, as listed in section 3.6, are expected to be more severe and more frequent. In case of overdose symptomatic treatment should be initiated.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 Withdrawal periods

Not applicable.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QM01AC06.

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-1 (COX-1).

4.3 Pharmacokinetics

If the cat is fasted when dosed, the maximal plasma concentrations are obtained after approximately 2 hours. If the cat is fed at the time of dosing, the absorption may be slightly delayed.
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.

Meloxicam is predominantly found in plasma and is also a major biliary excretion product whereas urine contains only traces of the parent compound. Five major metabolites were detected all having been shown to be pharmacologically inactive. Meloxicam is metabolised to an alcohol, an acid derivative and to several polar metabolites. As for other species investigated, the main pathway of meloxicam biotransformation in cat is oxidation.
Meloxicam is eliminated with a half-life of approximately 22 hours. The detection of metabolites from the parent compound in urine and faeces, but not in plasma is indicative for their rapid excretion. 21 % of the recovered dose is eliminated in urine (2 % as unchanged meloxicam, 19 % as metabolites) and 79 % in the faeces (49 % as unchanged meloxicam, 30 % as metabolites).

Mean peak concentration (C_{max}) after a dose of 0.5 mg was ~ 482 ng/ml and the area under curve (AUC_t) was ~15176 ng x h/ml.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Not applicable.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years

5.3 Special precautions for storage

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

5.4 Nature and composition of immediate packaging

OPA/Aluminium/PVC-Aluminium blisters containing 10 tablets.

Pack size:
Cardboard box of one blister of 10 tablets
Cardboard box of 3 blisters of 10 tablets
Cardboard box of 6 blisters of 10 tablets
Cardboard box of 9 blisters of 10 tablets
Cardboard box of 12 blisters of 10 tablets

Not all pack sizes may be marketed.

5.5 Special precautions for the disposal of unused veterinary medicinal product 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

Alfasan Nederland B.V.
Kuipersweg 9
3449 JA Woerden
The Netherlands

7. MARKETING AUTHORISATION NUMBER

Vm 36408/3016

8. DATE OF FIRST AUTHORISATION

19 December 2022

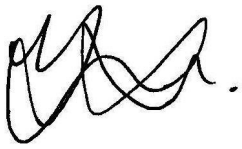
9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

December 2022

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).



Approved: 19 December 2022