SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Metaxx 0.5 mg/ml oral suspension for cats and guinea pigs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance:
Meloxicam 0.5 mg

Excipients:
Sodium benzoate (E211) 1.5 mg

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Yellow to light yellow oral suspension.

4. CLINICAL PARTICULARS

4.1 Target species

Cats, guinea pigs

4.2 Indications for use, specifying the target species

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

Guinea pigs:
Alleviation of mild to moderate post-operative pain associated with soft tissue surgery such as male castration.

4.3 Contraindications

Do not use in pregnant or lactating animals.
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.
Do not use in guinea pigs less than 4 weeks of age.

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.

Post-operative use in cats and guinea pigs:
In case additional pain relief is required, multimodal pain therapy should be considered.

Chronic musculoskeletal disorders in cats:
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 of the product may cause gastrointestinal effects, such as nausea and gastric pain. Avoid accidental ingestion by children. Do not leave the filled syringe unattended. Any uneaten medicated food must be disposed of immediately and the bowl washed thoroughly. In 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.

Other precautions
Not applicable.

4.6 Adverse reactions (frequency and seriousness)

Cats:

Frequency	Adverse event
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Appetite loss[1], lethargy[1], vomiting[1], diarrhoea[1], blood in faeces (occult)[1], gastric ulceration[1], small intestine ulcer[1]. Renal failure[1], elevated liver enzymes

[1] Typical adverse reactions of NSAIDs

These side effects are in most cases transient and disappear following termination of the treatment but may be serious or fatal.

Cats and guinea pigs:
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 also the package leaflet for respective contact details.

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).

Pregnancy and lactation:
Do not use in pregnant or lactating animals.

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.

In cats, 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.

4.9 Amount(s) to be administered and administration route

Oral use.
Particular care should be taken with regard to the accuracy of dosing. The recommended dose should not be exceeded.

Dosage
Cats:

Post-operative pain and inflammation following surgical procedures:
After initial treatment with a suitable injectable formulation of meloxicam authorised for cats, continue treatment 24 hours later with Metaxx 0.5 mg/ml oral suspension for cats 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.

Dosage
Guinea pigs:

Post-operative pain associated with soft tissue surgery:
Initial treatment is a single oral dose of 0.2 mg meloxicam/kg body weight on day 1 (pre-surgery).
Treatment is to be continued once daily by oral administration (at 24-hours intervals) at a dose of 0.1 mg meloxicam/kg body weight on day 2 to day 3 (post-surgery).

The dose can, at the discretion of the veterinarian, be titrated up to 0.5 mg/kg in individual cases. The safety of doses exceeding 0.6 mg/kg has, however, not been evaluated in guinea pigs.

Route and method of administration
To be administered either mixed with food (cats) or directly into the mouth (cats and guinea pigs) using the supplied 1 mL syringe graduated with ml scale and 0.02 mL increments.
Shake the bottle well before use, and avoid introduction of contamination during use.

Draw up the suspension according to the bodyweight of the animal.

Dose of 0.05 mg meloxicam/kg body weight:	0.1 mL/kg body weight
Dose of 0.1 mg meloxicam/kg body weight:	0.2 mL/kg body weight
Dose of 0.2 mg meloxicam/kg body weight:	0.4 mL/kg body weight

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

Meloxicam has a narrow therapeutic safety margin in cats 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.

In guinea pigs, an overdose of 0.6 mg/kg body weight administered during 3 days followed by a dose of 0.3 mg/kg during 6 additional days did not cause adverse events typical for meloxicam. The safety of doses exceeding 0.6 mg/kg has not been evaluated in guinea pigs.

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

Cats:

Absorption

If the animal is fasted when dosed with 0.2 mg/kg meloxicam, the maximal plasma concentration of 715 ng/ml (C_{max}) is reached after approximately 4 hours (T_{max}). If the animal is fed at the time of dosing, the absorption may be slightly delayed.

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.

Metabolism
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.

Elimination
Meloxicam is eliminated with a half-life of 19 hours ($t_{1/2}$). 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).

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium benzoate (E211)
Sorbitol, liquid (non crystallising)
Glycerol
Saccharin sodium
Xylitol
Sodium dihydrogen phosphate dihydrate
Silica, colloidal anhydrous
Xanthan gum
Citric acid monohydrate
Honey aroma
Water, purified

6.2 Major incompatibilities
In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale:
18 months (5 mL)
2 years (10 mL)
2 years (25 mL)
Shelf life after first opening the immediate packaging: 6 months

6.4 Special precautions for storage

5 ml: Store below 30°C. Do not refrigerate or freeze.
10 ml: Do not refrigerate or freeze.
25 ml: Do not refrigerate or freeze.

6.5 Nature and composition of immediate packaging

Cardboard box with one HDPE bottle with an LDPE syringe adapter and closed with a polypropylene screw cap.
Polypropylene measuring syringe of 1 mL.

Pack sizes:
5 ml (in a 10 ml sized bottle)
10 ml
25 ml

Not all pack sizes may be marketed.

6.6 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.
Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

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

8. MARKETING AUTHORISATION NUMBER

Vm 36408/5025

9. DATE OF FIRST AUTHORISATION

03 May 2024

10. DATE OF REVISION OF THE TEXT

May 2024

PROHIBITION OF SALE, SUPPLY AND/OR USE

POM-V

11. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCT

Veterinary medicinal product subject to prescription.

Find more product information by searching for the ‘Product Information Database’ or ‘PID’ on www.gov.uk.

Approved 03 May 2024