

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Metaxx 1.5 mg/ml oral suspension for dogs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance:

Meloxicam 1.5 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

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 animals 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 dogs less than 6 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.

This veterinary medicinal product for dogs should not be used in cats as it is not suitable for use in this species. In cats, Metaxx 0.5 mg/ml oral suspension for cats and guinea pigs should be used.

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)

Dogs:

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 occur generally within the first treatment week and are in most cases transient and disappear following termination of the treatment but 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 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.

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.

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 Amount(s) to be administered and administration route

Oral use.

Dosage

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.

For longer term treatment, once clinical response has been observed (after ≥ 4 days), the dose of the veterinary medicinal product can be adjusted to the lowest effective individual dose reflecting that the degree of pain and inflammation associated with chronic musculo-skeletal disorders may vary over time.

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

Route and method of administration

To be administered either mixed with food or directly into the mouth with the syringe.

Shake the bottle well before use, and avoid introduction of contamination during use.

Particular care should be taken with regard to the accuracy of dosing.

The suspension can be given using the measuring syringe provided in the package.

The syringe fits onto the drop dispenser of the bottle and has a kg-body weight scale which corresponds to the maintenance dose of 0.1 mg/kg body weight. Thus for initiation of the therapy on the first day, twice the maintenance volume will be required.

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 3.4 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 27 hours. Approximately 75 % of the administered dose is eliminated via faeces and the remainder via urine.

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: 30 months
Shelf life after first opening the immediate packaging: 6 months

6.4 Special precautions for storage

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 3 mL.

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

10 ml
25 ml
50 ml
125 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 36408/5026

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

