

*[Version 9,07/2021]*

## **ANNEX I**

### **SUMMARY OF PRODUCT CHARACTERISTICS**

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Metaxx 0.25 mg chewable tablets for cats (BE, BG, CY, CZ, DE, EL, ES, FR, HR, HU, IE, IT, LU, NL, PL, PT, RO, SI, SK, UK(NI))

Metaxx Vet 0.25 mg chewable tablets for cats (FI, IS, SE)

Mexxam Vet 0.25 mg chewable tablets for cats (AT, DK, EE, LT, LV, NO)

## 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.
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\* 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.

#### 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 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 BV

## **7. MARKETING AUTHORISATION NUMBER**

## **8. DATE OF FIRST AUTHORISATION**

Date of first authorisation: {DD/MM/YYYY}

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

{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) (<https://medicines.health.europa.eu/veterinary>).

**ANNEX II**

**LABELLING AND PACKAGE LEAFLET**



## **A. LABELLING**

**PARTICULARS TO APPEAR ON THE OUTER PACKAGE****CARTON BOX****1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Metaxx 0.25 mg chewable tablets

**2. STATEMENT OF ACTIVE SUBSTANCES**

Meloxicam                      0.25 mg

**3. PACKAGE SIZE**

10 tablets  
30 tablets  
60 tablets  
90 tablets  
120 tablets

**4. TARGET SPECIES**

Cats

**5. INDICATIONS****6. ROUTES OF ADMINISTRATION**

Oral use

**7. WITHDRAWAL PERIODS****8. EXPIRY DATE**

EXP. {month/year}

**9. SPECIAL STORAGE PRECAUTIONS****10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”**

Read the package leaflet before use.

<b>11. THE WORDS “FOR ANIMAL TREATMENT ONLY”</b>
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For animal treatment only.

<b>12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”</b>
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Keep out of the sight and reach of children.

<b>13. NAME OF THE MARKETING AUTHORISATION HOLDER</b>
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Alfasan Nederland BV

<b>14. MARKETING AUTHORISATION NUMBERS</b>
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<b>15. BATCH NUMBER</b>
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Lot {number}

<b>MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS</b> <b>ALUMINIUM BLISTER</b>
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<b>1. NAME OF THE VETERINARY MEDICINAL PRODUCT</b>
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Metaxx

<b>2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES</b>
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Meloxicam 0.25 mg

<b>3. BATCH NUMBER</b>
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Lot {number}

<b>4. EXPIRY DATE</b>
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Exp. {mm/yyyy}

## **B. PACKAGE LEAFLET**

## PACKAGE LEAFLET

### 1. Name of the veterinary medicinal product

Metaxx 0.25 mg chewable tablets for cats (BE, BG, CY, CZ, DE, EL, ES, FR, HR, HU, IE, IT, LU, NL, PL, PT, RO, SI, SK, UK(NI))

Metaxx Vet 0.25 mg chewable tablets for cats (FI, IS, SE)

Mexxam Vet 0.25 mg chewable tablets for cats (AT, DK, EE, LT, LV, NO)

### 2. Composition

Each tablet contains:

**Active substance:**

Meloxicam 0.25 mg

Chewable tablet

Light brown, slightly dotted, circular, biconvex, 7mm tablet with a cross-shaped break line on one side.

The tablets can be divided into two or four equal parts.

### 3. Target species

Cats

### 4. Indications for use

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.

### 5. 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.

### 6. Special warnings

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.

Pregnancy and lactation:

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

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.

Overdose (symptoms, emergency procedures, 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 adverse events, are expected to be more severe and more frequent. In case of overdose symptomatic treatment should be initiated.

## **7. 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.
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\* 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 product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system {national system details}.

## **8. Dosage for each species, routes and method of administration**

Oral use.

### 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 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

## **9. Advice on correct administration**

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.

## **10. Withdrawal periods**

Not applicable.

## **11. Special storage precautions**

Keep out of the sight and reach of children.

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

Do not use this veterinary medicinal product after the expiry date which is stated on the carton and the blister after EXP. The expiry date refers to the last day of that month.



## **12. Special precautions for disposal**

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 applicable national collection systems. These measures should help to protect the environment.

Ask your veterinary surgeon how to dispose of medicines no longer required.

### **UK(NI) only:**

Medicines should not be disposed of via wastewater. Any unused veterinary medicinal product should be disposed of in accordance with local requirements.

## **13. Classification of veterinary medicinal products**

Veterinary medicinal product subject to prescription.

## **14. Marketing authorisation numbers and pack sizes**

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.

## **15. Date on which the package leaflet was last revised**

{DD/MM/YYYY}

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

## **16. Contact details**

Marketing authorisation holder and manufacturer responsible for batch release and contact details to report suspected adverse reactions:

Alfasan Nederland BV

Kuipersweg 9

3449 JA Woerden

The Netherlands

Tel: +31 348 416945

E-mail: [pharmacovigilance@alfasan.nl](mailto:pharmacovigilance@alfasan.nl)

Manufacturer responsible for batch release:

LelyPharma BV

Zuiveringsweg 42

8243 PZ Lelystad

The Netherlands

Local representatives and contact details to report suspected adverse reactions:

**17. Other information**