

**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 AND OTHER SUBSTANCES**

Meloxicam 0.25 mg

**3. PACKAGE SIZE**

10 tablets  
30 tablets  
60 tablets  
90 tablets  
120 tablets

**4. TARGET SPECIES**



Cats

**5. INDICATION(S)**

**6. ROUTES OF ADMINISTRATION**

Oral use

**7. WITHDRAWAL PERIOD**

**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.

**11. THE WORDS “FOR ANIMAL TREATMENT ONLY”**

For animal treatment only.

**12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”**

Keep out of the sight and reach of children.

**13. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER**

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

**14. MARKETING AUTHORISATION NUMBER(S)**

Vm 36408/5010

**15. BATCH NUMBER**

Lot {number}

**16. SPECIAL WARNING(S), IF NECESSARY**

**17. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY**

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

**18. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE**

For animal treatment only.

POM-V

Prescription only

**MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS {ALUMINIUM  
BLISTER}**

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Metaxx

**2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCE(S)**

Each tablet contains:

Active substance:

Meloxicam 0.25 mg

**3. BATCH NUMBER**

Lot {number}

**4. EXPIRY DATE**

EXP {month/year}

**5. NAME OF THE MARKETING AUTHORISATION HOLDER**

Alfasan Nederland B.V.

**6. THE WORDS “FOR ANIMAL TREATMENT ONLY”**

For animal treatment only.

**PACKAGE LEAFLET FOR: Alfacam 0.25 mg chewable tablets for cats**

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Metaxx 0.25 mg chewable tablets for cats

**2. COMPOSITION**

Each tablet contains:

Active substance:  
Meloxicam 0.25 mg

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. 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 WARNING(S)**

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, ROUTE(S) 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 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.

The recommended dose should not be exceeded.

## 10. WITHDRAWAL PERIOD(S)

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 after EXP.

The expiry date refers to the last day of that month.

## 12. SPECIAL PRECAUTIONS FOR THE DISPOSAL

Dispose of waste material in accordance with local requirements.

Medicines should not be disposed of via wastewater.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required. These measures should help to protect the environment

## 13. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

POM-V

Prescription only

#### 14. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

Pack size:

OPA/Aluminium/PVC-Aluminium blisters containing 10 tablets

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 APPROVED

#### 16. CONTACT DETAILS

Marketing authorisation holder and manufacturer responsible for batch release:

Alfasan Nederland B.V.

Kuipersweg 9

3449 JA Woerden

The Netherlands

Manufacturer responsible for batch release:

LelyPharma BV

Zuiveringsweg 42

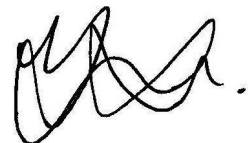
8243 PZ Lelystad

The Netherlands

Local representatives and contact details to report suspected adverse reactions:

#### 17. OTHER INFORMATION

Vm 36408/5010

A handwritten signature in black ink, consisting of several loops and a final horizontal stroke.

Approved: 19 December 2022