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.

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 OF THE MARKETING AUTHORISATION HOLDER

Alfasan Nederland B.V.

14. MARKETING AUTHORISATION NUMBERS

Vm 36408/3016

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

ALUMINIUM BLISTER

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Metaxx

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Meloxicam 0.25 mg

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

B. PACKAGE LEAFLET

PACKAGE LEAFLET

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, 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.

* 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).

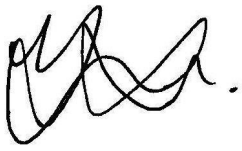
16. Contact details

Marketing authorisation holder and manufacturer responsible for batch release and contact details to report suspected adverse reactions:
Alfasan Nederland B.V.
Kuipersweg 9
3449 JA Woerden
The Netherlands
Tel: +31 348 416945
E-mail: 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



Approved: 19 December 2022