ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Cardboard box

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Metaxx 0.5 mg/ml oral suspension

2. STATEMENT OF ACTIVE SUBSTANCES

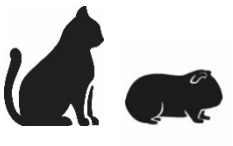
Meloxicam 0.5 mg/ml

3. PACKAGE SIZE

5 mL
10 mL
25 mL

4. TARGET SPECIES

Cats and guinea pigs.



5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Oral use.

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp. {mm/yyyy}

Once broached use within 6 months.

9. SPECIAL STORAGE PRECAUTIONS

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.

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 36408/3029

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Bottle of 5 mL, 10 mL or 25 mL

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Metaxx

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Meloxicam 0.5 mg/ml

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

Once broached use within 6 months.

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

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

2. Composition

Each ml contains:

Active substance:

Meloxicam 0.5 mg

Excipients:
Sodium benzoate (E211) 1.5 mg

Yellow to light yellow oral suspension.

3. Target species

Cats, guinea pigs.

4. Indications for use

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.

5. 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.

6. Special warnings

Special precautions for safe use in the target species:
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.

Pregnancy and lactation:
The safety of the veterinary medicinal product has not been established during pregnancy and lactation. Do not use in pregnant or lactating animals.

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. Concurrent administration of potential nephrotoxic drugs should be avoided.

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.

Overdose:
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 the section on adverse events, 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.

Special restrictions for use and special conditions for use:
Not applicable.

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

7. Adverse events

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], Gastrointestinal ulceration[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 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 or the local representative of the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system.

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

Oral use.

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, i.e. 0.1 mL/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, i.e. 0.4 mL/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, i.e. 0.1 mL/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, i.e. 0.2 mL/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, i.e. 0.1 mL/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, i.e. 0.4 mL/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, i.e. 0.2 mL/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 body weight, i.e. 1 mL/kg body weight in individual cases. The safety of doses exceeding 0.6 mg/kg body weight 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.
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

9. Advice on correct administration

Particular care should be taken with regard to the accuracy of dosing. Shake the bottle well before use, and avoid introduction of contamination during use. The recommended dose should not be exceeded.

10. Withdrawal periods

Not applicable.

11. Special storage precautions

Keep out of the sight and reach of children.
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.
Do not use this veterinary medicinal product after the expiry date which is stated on the carton and bottle after Exp. The expiry date refers to the last day of that month.
Shelf life after first opening the immediate packaging : 6 months.

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 or pharmacist how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

Vm 36408/3029

5 mL (in a 10 ml sized bottle)
10 mL
25 mL

Not all pack sizes may be marketed.

15. PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]
Find more product information by searching for the ‘Product Information Database’ on www.gov.uk.

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

Manufacturer responsible for batch release:
Produlab Pharma BV
Forellenweg 16
4941 SJ Raamsdonksveer
The Netherlands

Local representatives and contact details to report suspected adverse reactions

None

17. Other information

Approved 03 May 2024