ANNEX II

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Carton for 125 ml and 336 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Metaxx 15 mg/ml oral suspension

2. STATEMENT OF ACTIVE SUBSTANCES

Active substance:
Meloxicam 15 mg/ml

3. PACKAGE SIZE

125 ml
336 ml

4. TARGET SPECIES

Horses

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Oral use.

Read the package leaflet before use.

7. WITHDRAWAL PERIODS

Withdrawal periods:
Meat and offal: 3 days.
Not authorised for use in horses producing milk for human consumption.

8. EXPIRY DATE

Exp. {month/year}
Once opened use within 6 months.

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 BV

14. MARKETING AUTHORISATION NUMBERS

Vm 36408/3010

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

Bottle, 125 ml and 336 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Metaxx 15 mg/ml oral suspension for horses

2. STATEMENT OF ACTIVE SUBSTANCES

Active substance:
Meloxicam 15 mg/ml

3. TARGET SPECIES

Horses

4. ROUTES OF ADMINISTRATION

Oral use

Read the package leaflet before use.

5. WITHDRAWAL PERIODS

Withdrawal period:
Meat and offal: 3 days.
Not authorised for use in horses producing milk for human consumption.

6. EXPIRY DATE

Exp. {month/year}
Once opened use within 6 months.
Once opened, use by: ----- / -----

7. SPECIAL STORAGE PRECAUTIONS

8. NAME OF THE MARKETING AUTHORISATION HOLDER

Alfasan Nederland BV

9. BATCH NUMBER

Lot {number}

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Metaxx 15 mg/ml oral suspension for horses

2. Composition

One ml contains:

Active substance:
Meloxicam 15.0 mg

Excipients:
Sodium benzoate (E211) 1.5 mg

Yellow to light yellow suspension.

3. Target species

Horses

4. Indications for use

Alleviation of inflammation and relief of pain in both acute and chronic musculo-skeletal disorders in horses.

5. Contraindications

Do not use in pregnant or lactating mares.
Do not use in horses 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 horses less than 6 weeks of age.

6. Special warnings

Special precautions for use in animals
Avoid use in any dehydrated, hypovolaemic or hypotensive horses as there is a potential risk of renal toxicity.

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 (allergic reactions). People with known hypersensitivity to Non-

Steroidal Anti-Inflammatory Drugs (NSAIDs) should avoid contact with the veterinary medicinal product.

Avoid oral exposure, including hand-to-mouth contact. Wash hands after use.
In case of accidental ingestion, seek medical advice immediately and show the package leaflet or the label to the physician.

This veterinary medicinal product can cause eye irritation. In case of contact with the eyes, immediately rinse thoroughly with water.

Meloxicam may have adverse effects on pregnancy and/or embryofoetal development. Avoid dermal exposure including hand-to-mouth contact. Pregnant women or women attempting to conceive should wear impermeable gloves when administering the veterinary medicinal product.

Pregnancy and lactation:
See section “Contraindications”.

Interaction with other medicinal products and other forms of interaction:
Do not administer concurrently with glucocorticoids, other non-steroidal anti-inflammatory drugs or with anticoagulant agents.

Overdose :
In case of overdose symptomatic treatment should be initiated.

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

7. Adverse events

Horses:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Diarrhoea* Appetite loss Lethargy Abdominal pain Colitis Urticaria. Anaphylactoid reaction**

* Diarrhoea, typically associated with NSAIDs, was very rarely observed in clinical trials. The clinical sign was reversible
**Anaphylactoid reactions, which may be serious (including fatal), have been observed very rarely from post-marketing safety experience and should be treated symptomatically.

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 {national system details}.

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

Oral use.

To be administered either mixed with food or directly into the mouth at a dosage of 0.6 mg/kg (=0.04 ml/kg) body weight, once daily, up to 14 days. In case the veterinary medicinal product is mixed with food, it should be added to a small quantity of food, prior to feeding.

The suspension should be given using the measuring syringe provided in the package. The syringe fits onto the bottle and has volume scale and a “kg-body weight” scale which corresponds to the maintenance dose (i.e. 0.6 mg meloxicam / kg body weight).

To ensure administration of a correct dose, body weight should be determined as accurately as possible.

Shake well for approximately 60 seconds before use.

After administration of the veterinary medicinal product, close the bottle by replacing the cap, wash the measuring syringe with warm water and let it dry.

9. Advice on correct administration

Avoid introduction of contamination during use.

10. Withdrawal periods

Meat and offal: 3 days.
Not authorised for use in horses producing milk for human consumption.

11. Special storage precautions

Keep out of the sight and reach of children.
This veterinary medicinal product does not require any special storage conditions.
Shelf-life after first opening of the immediate packaging: 6 months.
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 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.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

Cardboard box with 1 bottle of 125 ml and a measuring syringe of 24 ml
Cardboard box with 1 bottle of 336 ml and a measuring syringe of 24 ml
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 BV
Kuipersweg 9
3449 JA Woerden
The Netherlands
Tel: +31-(0)348-453757

Additional 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>:

17. Other information

<national information>

Approved 12 January 2023