SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Metaxx 15 mg/ml oral suspension for horses

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

One ml contains:

Active substance:
Meloxicam 15.0 mg

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Sodium benzoate (E211)	1.5 mg
Glycerol	n.a.
Saccharin sodium	n.a.
Xylitol	n.a.
Sodium dihydrogen phosphate dihydrate	n.a.
Silica, colloidal anhydrous	n.a.
Sorbitol, liquid (non-crystallising)	n.a.
Xanthan gum	n.a.
Citric acid monohydrate	n.a.
Honey aroma	n.a.
Purified water or water for injections	n.a

Oral suspension.
Yellow to light yellow suspension.

3. CLINICAL INFORMATION

3.1 Target species

Horses

3.2 Indications for use for each target species

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

3.3 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.

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 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.

Special precautions for the protection of the environment:
Not applicable.

3.6 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 veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder <or its local representative> or the national competent authority via the national reporting system. See also section 16 of the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

The safety of the veterinary medicinal product has not been established during pregnancy and lactation. The use is not recommended during pregnancy and lactation. Laboratory studies in cattle have not produced any evidence for teratogenic, foetotoxic, or maternotoxic effects.

3.8 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.

3.9 Administration routes and dosage

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.

Avoid introduction of contamination during use.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

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

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

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. Meloxicam also has anti-endotoxic properties because it has been shown to inhibit production of thromboxane B_2 induced by intravenous *E. coli* endotoxin administration in calves and pigs.

4.3 Pharmacokinetics

Absorption
When the veterinary medicinal product is used according to the recommended dosage regime the oral bioavailability is approximately 98 %. Maximal plasma concentrations are obtained after approximately 5–6 hours. The accumulation factor of 1.08 suggests that meloxicam does not accumulate when administered daily.

Distribution
Approximately 98 % of meloxicam is bound to plasma proteins. The volume of distribution is
0.12 l/kg.

Metabolism
The metabolism is qualitatively similar in rats, mini-pigs, humans, cattle and pigs although quantitatively there are differences. The major metabolites found in all species were the 5-hydroxy- and 5-carboxy- metabolites and the oxalyl-metabolite. The metabolism in horses was not investigated. All major metabolites have been shown to be pharmacologically inactive.

Elimination
Meloxicam is eliminated with a terminal half-life of 7.7 hours.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

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

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years
Shelf life after first opening the immediate packaging: 6 months

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

High density polyethylene bottle with a polypropylene tamper-proof child-resistant screw cap and a polypropylene measuring syringe.

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.

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 B.V.
Kuipersweg 9
3449 JA Woerden
The Netherlands

7. MARKETING AUTHORISATION NUMBER

Vm 36408/3010

8. DATE OF FIRST AUTHORISATION

12 January 2023

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

January 2023

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).

Approved 12 January 2023