SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Triquest 333 mg/ml + 67 mg/ml oral suspension for horses

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substances:

Sulfadiazine	333 mg
Trimethoprim	67 mg

Excipients

Qualitative composition of excipients and other constituents
Xanthan gum
Sucralose
Sodium hydroxide
Anise aroma
Hydrochloric acid, concentrated (for pH adjustment)
Purified water

Opaque off white to yellow oral suspension.

3. CLINICAL INFORMATION

3.1 Target species

Horses

3.2 Indications for use for each target species

For the treatment of infections in horses caused by micro-organisms susceptible to the combination of trimethoprim and sulfadiazine, such as infections of the upper respiratory tract, the urogenital system and wound infections.

3.3 Contraindications

Do not use in cases of hypersensitivity to the active substances or to any of the excipients.
Do not use in animals with severe kidney or liver damage.

3.4 Special warnings

Cross-resistance has been shown between sulfadiazine and other sulfonamides. Use of the veterinary medicinal product should be carefully considered when susceptibility testing has shown resistance to sulfonamides because its effectiveness may be reduced.
In case of infections involving purulent conditions, trimethoprim-sulfonamides combinations are not recommended due to a diminished efficacy under such conditions.

3.5 Special precautions for use

Special precautions for safe use in the target species:
Caution should be exercised when treating new-born animals and animals with liver damage.
Renal impairment leads to risk of accumulation, increasing the risk of side effects in long term treatment.
Throughout the treatment, animals should have free access to drinking water to avoid possible crystalluria.
Use the veterinary medicinal product cautiously in horses with blood dyscrasias.

Use of the veterinary medicinal product should be based on identification and susceptibility testing of the target pathogen(s). If this is not possible, therapy should be based on epidemiological information and knowledge of susceptibility of the target pathogens at farm level, or at local/regional level.
Use of the veterinary medicinal product should be in accordance with official, national and regional antimicrobial policies.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
This veterinary medicinal product contains sulfadiazine, a sulfonamide which can cause hypersensitivity reactions following skin contact or accidental ingestion.
Hypersensitivity to sulfonamides may lead to cross reactions with other antibiotics.
Allergic reactions to sulfonamides may occasionally be serious. This veterinary medicinal product may also cause skin or eye irritation.
Skin and eye contact with the veterinary medicinal product should be avoided. This is especially important for people with known hypersensitivity to sulfonamides.
In the case of contact with skin, wash with soap and water. In the case of contact with the eyes, wash with water.
If symptoms develop following exposure such as a skin rash or difficulty with breathing and irritation persists, seek medical advice immediately and show the package leaflet or the label to the physician.
Wash hands thoroughly after use.

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

3.6 Adverse events

Horses:

Common (1 to 10 animals / 100 animals treated):	Digestive tract disorder (e.g. loose stool, diarrhoea, colitis).
Undetermined frequency (cannot be estimated from the available data)	Hypersensitivity reaction (e.g. urticaria). Inappetence. Hepatic disorder. Renal disorder, renal tubular disorder.[1] Haematologic effects (e.g. anaemia, thrombocytopenia, or leucopenia), haematuria, crystalluria.

[1] tubular obstruction

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 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.

Pregnancy and lactation
Laboratory studies in rats and rabbits have shown evidence of teratogenic effects at dosages that are above therapeutic dosages.
Do not use in pregnant and lactating mares.

3.8 Interaction with other medicinal products and other forms of interaction

Potentiated sulfonamides can cause fatal arrhythmias in horses sedated with alpha2-adrenoceptor agonists.

3.9 Administration routes and dosage

Oral use.

The recommended dose per administration is 30 mg of the active substances together (i.e. 5 mg trimethoprim and 25 mg sulfadiazine) per kg bodyweight, corresponding to 7.5 ml of the veterinary medicinal product per 100 kg bodyweight, 1 or 2 times per day. Frequency of dosing is decided on basis of the susceptibility of the pathogens involved and location of the infection. Treatment should continue for five days or until two days after the horse is free of symptoms up to a maximum of five days.

Medication may be administered in the morning before offering the morning ration. Similarly, when dosed twice daily the second dose may be administered before providing the evening ration.

To ensure a correct dosage, body weight should be determined as accurately as possible. One syringe is intended for up to 300 kg body weight and each syringe is subdivided into 11 markings. The equivalent of one marking is sufficient to treat 25 kg of body weight and the minimum body weight for treatment is 50 kg.

Before drawing up the dose in the syringe, the bottle should be shaken vigorously.

The veterinary medicinal product is administered orally by inserting the nozzle of the syringe applicator through the interdental space and depositing the required amount of veterinary medicinal product on the back of the tongue. Immediately after administration, elevate the head of the horse for a few seconds to ensure the dose is swallowed.

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

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

In case of an overdose loose faeces or diarrhoea may be observed. This is generally self-limiting, but if needed can be treated symptomatically e.g. fluid therapy in case of dehydration.

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: 20 days

Milk: Not authorised for use in animals producing milk for human consumption.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QJ01EW10

4.2 Pharmacodynamics

Sulfadiazine is a bacteriostatic antibiotic belonging to the sulfonamide group which acts by interference with the synthesis of nucleic acids. Trimethoprim is a reductase inhibitor which also interferes with the synthesis of bacterial nucleic acids. Trimethoprim and sulfadiazine each have a bacteriostatic action, but together they have a synergistic bactericidal effect by intervening in two consecutive steps of the

bacterial folate metabolism. The combination of trimethoprim and sulfadiazine has a broad antibacterial spectrum for both gram positive and gram negative bacteria. Chromosomal mutation and plasmid-mediated resistance are described for sulfonamides and its combinations. Resistance is widespread among bacteria isolated from animals reflecting extensive use over time. There is complete cross-resistance between sulfonamides.

4.3 Pharmacokinetics

Following a single oral administration of the veterinary medicinal product to horses at a dose of 30 mg/kg BW (5 mg/kg trimethoprim and 25 mg/kg sulfadiazine) the mean peak plasma concentration (C_{max}) was 1.8 mcg/ml for trimethoprim and 19 mcg/ml for sulfadiazine, and was reached after a median of 1.8 hours (T_{max} ranged from 0.67 to 4 hours) for trimethoprim and 3 hours (T_{max} ranged from 0.67 to 9 hours) for sulfadiazine.
Both substances are metabolized in the liver; sulfadiazine by acetylation and glucuronidation and trimethoprim by hydroxylation and glucuronidation. Excretion is primarily by the kidney, only to a lesser extent in the faeces.
The plasma elimination half-life for trimethoprim was approximately 2 hours and for sulfadiazine was approximately 6 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: 30 days

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

White HDPE bottle containing 225 ml suspension or 450 ml suspension closed with a white tamper-proof PP screw-cap including a LDPE plug.
Each bottle is packed in a carton box and equipped with a PP oral syringe.
Not all pack sizes may be marketed.

5.5 Special precautions for the disposal of unused veterinary medicinal products 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.

7. MARKETING AUTHORISATION NUMBER

Vm 36408/3039

8. DATE OF FIRST AUTHORISATION

21 August 2024

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

August 2024

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)*.

Gavin Hall

Approved: 21 August 2024