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:
For the full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Oral suspension
Opaque off white to yellow suspension.

4. CLINICAL PARTICULARS

4.1 Target species

Horses.

4.2 Indications for use, specifying the 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.

4.3 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.

4.4 Special warnings for each target species

The use of the veterinary medicinal product in horses under 1 year old should be avoided.
Cross-resistance has been shown between sulfadiazine and other sulfonamides. Use of the 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.

4.5 Special precautions for use

Special precautions for use in animals
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 take by the person administering the veterinary medicinal product to animals

This product contains sulfadiazine, a sulfonamide which can cause hypersensitivity (allergic) 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.
If symptoms develop following exposure, such as a skin rash or difficulty with breathing, seek medical advice immediately and show the package leaflet or the label to the physician.

This product may cause gastrointestinal disturbances, or irritation of the skin and eyes, after exposure. Wearing impervious gloves is recommended when administering the product. In the case of contact with skin, wash with soap and water. In the case of contact with the eyes, rinse thoroughly with water.

Special precautions for the protection of the environment:
Not applicable

Other precautions
Not applicable.

4.6 Adverse reactions (frequency and seriousness)

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 reactions such as urticaria. Inappetence. Hepatic or renal disorders. Hematologic effects, such as anaemia, thrombocytopenia, or leukopenia. Haematuria, crystalluria, 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 also section 16 of the package leaflet for respective contact details.

4.7 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

4.8 Interaction with other medicinal products and other forms of interaction

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

4.9 Amount(s) to be administered and administration route

Oral use.

The recommended dose 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, once daily or divided and administered at 12 hourly intervals. 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 to avoid underdosing. 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 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 tightly with the cap, wash the syringe with water and let it dry. Do not use the same syringe in more than one animal.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

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.

4.11 Withdrawal period

Meat and offal: 6 months
Milk: Not authorised for use in mares producing milk for human consumption

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Sulfonamides and trimethoprim

ATC Vet Code: QJ01EW10

5.1 Pharmacodynamic properties

Sulfadiazine is a bacteriostatic antibiotic belonging to the sulphonamide 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 sulphonamides and its combinations. Resistance is widespread among bacteria isolated from animals reflecting extensive use over time. There is complete cross-resistance between sulphonamides.

5.2 Pharmacokinetic particulars

Following a single oral administration of the veterinary medicinal product to horses at a dose of 30 mg/kg BW (5 mg/kg TMP and 25 mg/kg SDZ) the mean peak plasma concentration (C_{max}) was 1821.06 ng/ml for TMP and 19235.74 ng/ml for SDZ, and was reached after a median of 1.8 hours (T_{max} ranged from 0.67 to 4 hours) for TMP and a median of 3 hours (T_{max} ranged from 0.67 to 9 hours) for SDZ.

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 TMP was 2.4 hours and for SDZ was 6.1 hours.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Xanthan gum
Sucralose
Sodium hydroxide
Anise aroma
Hydrochloric acid
Purified water

6.2 Major Incompatibilities

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

6.3 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

6.4 Special precautions for storage

This veterinary medicinal product does not require any special storage conditions.

6.5 Nature and composition of immediate packaging

White HDPE bottle of 250 ml (containing 225 ml suspension) or 500 ml (containing 450 ml suspension) closed with a white tamper-proof child resistant PP cap including a LDPE plug cap.
Each bottle is packed in a carton box and equipped with a PP syringe applicator.
Not all pack sizes may be marketed.

6.6 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. Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

Alfasan Nederland BV
Kuipersweg 9
3449 JA Woerden
The Netherlands

8. MARKETING AUTHORISATION NUMBER

Vm 36408/5029

9. DATE OF FIRST AUTHORISATION

09 August 2024

10. DATE OF REVISION OF THE TEXT

August 2024

PROHIBITION OF SALE, SUPPLY AND/OR USE

11. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.'

Find more product information by searching for the 'Product Information Database' or 'PID' on www.gov.uk.

Gavin Hall

Approved: 09 August 2024