PARTICULARS TO APPEAR ON THE OUTER PACKAGE {CARTON BOX}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Sulfadiazine	333.0 mg
Trimethoprim	67.0 mg

3. PACKAGE SIZE

250 ml
500 ml

4. TARGET SPECIES

Horses

5. INDICATION(S)

6. ROUTES OF ADMINISTRATION

Oral suspension

7. WITHDRAWAL PERIODS

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

8. EXPIRY DATE

Exp. {mm/yyyy}
Once opened use within 30 days.
Once opened use by….

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 B.V.

14. MARKETING AUTHORISATION NUMBERS

Vm 36408/5029

15. BATCH NUMBER

Lot {number}

16. SPECIAL WARNING(S), IF NECESSARY

17. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: Read package leaflet

18. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE {HDPE bottles}

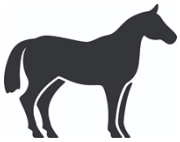
1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Sulfadiazine	333.0 mg
Trimethoprim	67.0 mg

3. TARGET SPECIES



4. ROUTES OF ADMINISTRATION

Oral suspension

5. WITHDRAWAL PERIODS

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

6. EXPIRY DATE

Exp. {mm/yyyy}
Once opened use within 30 days.
Once opened use by….

7. SPECIAL STORAGE PRECAUTIONS

Keep the bottle in the outer carton.

8. NAME OF THE MARKETING AUTHORISATION HOLDER

Alfasan Nederland B.V.

9. BATCH NUMBER

Lot {number}

10. SPECIAL WARNING(S), IF NECESSARY

11. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

12. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE

For animal treatment only.

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. COMPOSITION

Each ml contains:

Active substances:

Sulfadiazine	333 mg
Trimethoprim	67 mg

Oral suspension
Opaque off white to yellow suspension.

3. TARGET SPECIES

Horses.

4. INDICATIONS FOR USE

Treatment of infections in horses caused by bacteria sensitive to the combination of trimethoprim and sulfadiazine, including:
Respiratory tract infections associated with *Streptococcus* spp. and *Staphylococcus aureus*;
Gastrointestinal infections associated with *E. coli*;
Wound infections associated with *Streptococcus* spp. and *Staphylococcus aureus*.

5. CONTRAINDICATIONS

Do not use in horses with severe liver parenchymal damage or kidney damage or known sulphonamide sensitivity, or horses with blood dyscrasias or cardiac arrhythmias.
Do not exceed 7 days continuous treatment

6. SPECIAL WARNINGS

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

Special precautions for use in animals
To avoid possible crystalluria, adequate water intake is essential.
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 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.

Use during pregnancy, lactation or lay
In the rat and the rabbit, trimethoprim/sulfadiazine combinations did not produce any foetal abnormalities at doses of up to 600 mg/kg, although minor effects on skeletal development were seen below this level. As no studies have been conducted in horses, use on pregnant mares should be avoided.

When administered to lactating females, small amounts of trimethoprim and sulfadiazine are present in the maternal milk. Since no studies have been reported on the effects of the veterinary medicinal product on the development of new born foals, it would be prudent not to feed very young foals with milk obtained from mares being treated.

Interaction with other medicinal products and other forms of interaction
None known

Overdose
No information available. As there is no specific antidote, treatment should be symptomatic

7. ADVERSE EVENTS

Horses:

Common (1 to 10 animals / 100 animals treated):	GI disturbances such as diarrhoea.
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.

8. DOSAGE FOR EACH SPECIES, ROUTES AND METHOD OF ADMINISTRATION

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.

Treatment should continue for 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.

9. ADVICE ON CORRECT ADMINISTRATION

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.

10. WITHDRAWAL PERIODS

Meat and offal: 6 months
Milk: Not authorised for use in mares 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.
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 container: 30 days.

12. SPECIAL PRECAUTIONS FOR DISPOSAL

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.
Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required. 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

Vm 36408/5029

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.

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 reaction:
Alfasan Nederland BV
Kuipersweg 9
3449 JA Woerden
The Netherlands.

Manufacturer responsible for batch release:
LelyPharma B.V.
Zuiveringsweg 42
8243 PZ Lelystad
The Netherlands

Local representatives and contact details to report suspected adverse reactions:

17. OTHER INFORMATION

Gavin Hall

Approved: 09 August 2024