LABELLING

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 SUBSTANCES

Each ml contains

Sulfadiazine	333 mg
Trimethoprim	67 mg

3. PACKAGE SIZE

225 ml
450 ml

4. TARGET SPECIES

Horses

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Oral suspension

7. WITHDRAWAL PERIODS

Withdrawal period:
Meat and offal: 20 days
Milk: Not authorised for use in animals 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 36408/3039

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

HDPE bottles of 225 ml or 450 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:

Sulfadiazine	333 mg
Trimethoprim	67 mg

3. TARGET SPECIES

Horses

4. ROUTES OF ADMINISTRATION

Oral suspension
Read the package leaflet before use.

5. WITHDRAWAL PERIODS

Withdrawal period:
Meat and offal: 20 days
Milk: Not authorised for use in animals producing milk for human consumption.

6. EXPIRY DATE

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

7. SPECIAL STORAGE PRECAUTIONS

8. NAME OF THE MARKETING AUTHORISATION HOLDER

Alfasan Nederland B.V.

9. BATCH NUMBER

Lot {number}

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

Opaque off white to yellow oral suspension.

3. Target species

Horses

4. Indications for use

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.

5. 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.

6. Special warnings

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.

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.

Pregnancy and lactation:
The safety of the veterinary medicinal product has not been established during 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.

Interaction with other medicinal products and other forms of interaction:
Potentiated sulfonamides can cause fatal arrhythmias in horses sedated with alpha2-adrenoceptor agonists.

Overdose:
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.

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:

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 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.

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.

9. Advice on correct administration

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.

10. Withdrawal periods

Meat and offal: 20 days

Milk: Not authorised for use in animals 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 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.

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

UK(NI) only:
Medicines should not be disposed of via wastewater. Any unused veterinary medicinal product should be disposed of in accordance with local requirements.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

Vm 36408/3039

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.

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 B.V.
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: 21 August 2024