1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Trimediazine Plain Oral Powder

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each gram contains:

Active substances:

Trimethoprim 50 mg
Sulfadiazine 250 mg

Excipients:

Qualitative composition of excipients and other constituents
Silica colloidal anhydrous
Glucose monohydrate

White oral powder.

3. CLINICAL INFORMATION

3.1 Target species

Horses.

3.2 Indications for use for each target species

The veterinary medicinal product is indicated for use in the treatment of bacterial diseases in horses, including upper and lower respiratory tract infections, alimentary tract infections and infected wounds.

3.3 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.

3.4 Special warnings

The use of the veterinary medicinal product in horses under 1 year old should be avoided.

3.5 Special precautions for use

Special precautions for safe use in the target species:

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 bacteria 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:

Persons handling this veterinary medicinal product should avoid inhalation of any dust and contact with skin. Personal protective equipment consisting of a disposable half-mask respirator conforming to European Standard to EN149 or a non-disposable respirator to European Standard to EN140 with filter EN143 should be worn when mixing or handling the veterinary medicinal product. Rubber gloves should be worn when mixing or handling this veterinary medicinal product. Hands should be washed thoroughly after use. Sulphonamides may cause hypersensitivity (allergy) following injection, inhalation, ingestion or skin contact.
Hypersensitivity to sulphonamides may lead to cross reactions with other antibiotics. Allergic reactions to these substances may occasionally be serious.

People with known hypersensitivity to sulphonamides should avoid contact with the veterinary medicinal product.
If you develop symptoms following exposure such as a skin rash, seek medical advice and show the package leaflet or the label to the physician.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

None known.

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

Pregnancy and lactation:

Laboratory studies in the rat and the rabbit have not produced any evidence of 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.

3.8 Interaction with other medicinal products and other forms of interaction

None known

3.9 Administration routes and dosage

Oral use. For administration in the feed.

To ensure a correct dosage, body weight should be determined as accurately as possible.

To be given at a rate of 30 mg combined active ingredients per kg bodyweight.

Mix with a small quantity of feed. Each 50 g sachet provides a daily dose for a 500 kg horse and may be administered daily or divided and administered at 12 hourly intervals, for 5 days.

It is recommended that other feed be withdrawn until medicated feed has been consumed.

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

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

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: 6 months

4. PHARMACOLOGICALINFORMATION

4.1 ATCvet code: QJ01EW10

4.2 Pharmacodynamics

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.
Sulfadiazine and trimethoprim act on the same metabolic pathway, resulting in potentiation of antibacterial activity.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

None known.

5.2 Shelf life

Add to feed immediately before administration. Discard any remaining medicated feed.

Shelf-life of the veterinary medicinal product as packaged for sale: 18 months.

5.3 Special precautions for storage

Do not store above 25 ^{0}C.
Store in a dry place away from animal feeding stuffs.

5.4 Nature and composition of immediate packaging

Heat sealed metallised polyester sachet containing 50 g of powder.
Presented in cartons containing 10 x 50 g sachets.

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

Vetoquinol S.A.

7. MARKETING AUTHORISATION NUMBER(S)

VPA10521/035/001

8. DATE OF FIRST AUTHORISATION

01/10/1988

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

19/06/2026

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).