PARTICULARS TO APPEAR ON THE OUTER PACKAGE - CARTON

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Trimediazine Plain Oral Powder

2. STATEMENT OF ACTIVE SUBSTANCES

Each gram contains:

Trimethoprim 50 mg

Sulfadiazine 250 mg

3. PACKAGE SIZE

10 x 50 g sachets

4. TARGET SPECIES

Horses

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Oral use.

7. WITHDRAWAL PERIODS

Withdrawal periods:

Meat and offal: 6 months

8. EXPIRY DATE

Exp. {mm/yyyy}

9. SPECIAL STORAGE PRECAUTIONS

Do not store above 25ºC
Store in a dry place away from animal feeding stuffs.

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

Vetoquinol SA

14. MARKETING AUTHORISATION NUMBERS

Vm 06462/3012

15. BATCH NUMBER

Lot {number}

Vetoquinol logo

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE - SACHET

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Trimediazine Plain Oral Powder

2. STATEMENT OF ACTIVE SUBSTANCES

Each gram contains:

Trimethoprim 50 mg

Sulfadiazine 250 mg

3. TARGET SPECIES

Horses

4. ROUTES OF ADMINISTRATION

Oral use.

Read the package leaflet before use.

5. WITHDRAWAL PERIODS

Withdrawal periods:

Meat and offal: 6 months

6. EXPIRY DATE

Exp. {mm/yyyy}

7. SPECIAL STORAGE PRECAUTIONS

Do not store above 25ºC

Store in a dry place away from animal feeding stuffs

8. NAME OF THE MARKETING AUTHORISATION HOLDER

Vetoquinol SA

9. BATCH NUMBER

Lot {number}

Vetoquinol logo

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:
PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Trimediazine Plain Oral Powder

2. Composition

Each gram contains:

Active substances:

Trimethoprim.	50 mg
Sulfadiazine.	250 mg

White oral powder.

3. Target species

Horses

4. Indications for use

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.

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

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

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. Use of the veterinary medicinal product deviating from the instructions given in the SPC may increase the prevalence of bacteria resistant to the product, and may decrease the effectiveness of treatment with other antimicrobials or classes of antimicrobials due to the potential for cross-resistance.

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 this 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.

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 newborn 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.

Major incompatibilities:

None known.

7. Adverse events

None known.

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 using the contact details at the end of this leaflet, or via your national reporting system at:

Website: https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine

e-mail: adverse.events@vmd.gov.uk

8. Dosage for each species, routes and method of administration

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.

9. Advice on correct administration

10. Withdrawal periods

Meat and offal: 6 months

11. Special storage precautions

Keep out of the sight and reach of children.

Do not store above 25˚C. Store in a dry place away from animal feeding stuffs.

Do not use this veterinary medicinal product after the expiry date which is stated on the label or carton after Exp. The expiry date refers to the last day of that month.

12. Special precautions for disposal

Medicines should not be disposed of via wastewater.

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.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

Vm 06462/3012

Heat sealed metallised polyester sachet containing 50 g of powder.

Cardboard box containing 10 x 50 g sachets.

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 contact details to report suspected adverse reaction:

Vetoquinol SA
34 Rue de Chene Sainte-Anne
Magny-Vernois
70200 Lure
France

Tel : +44 (0)1280 814 500

Manufacturer responsible for batch release:
Vetoquinol Biowet Sp. z o.o.
ul. Kosynierów Gdyńskich 13-14
66-400 Gorzów Wielkopolski

17. Other information

POM-V

Vetoquinol logo

Gavin Hall
Approved: 05 June 2026