

**PARTICULARS TO APPEAR ON THE OUTER PACKAGE - CARTON
TRIMEZIADINE PASTE ORAL PASTE**

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Trimediazine Paste ORAL PASTE

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each 45g syringe contains:
Trimethoprim 2.6g and Sulfadiazine 13.0g and as preservatives:
Methyl hydroxybenzoate 81mg and Propyl Hydroxybenzoate 9mg.

3. PHARMACEUTICAL FORM

Oral paste.

4. PACKAGE SIZE

45g.

5. TARGET SPECIES

Horses.

6. INDICATION(S)

Trimediazine Paste is indicated in the treatment of bacterial infections in horses caused by sensitive micro-organisms including: *Escherichia coli*, *Rhodococcus equi*, *Staphylococcus* spp., *Streptococcus* spp.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Adjust screw gauge on dial-a-dose plunger to the bodyweight of the horse. Remove cap from nozzle. Place nozzle in the corner of mouth. Depress plunger depositing paste on upper surface of tongue. The daily dose is 30mg of combined actives per kg bodyweight by oral administration.

Treatment should be continued for up to 5 days or until 2 days after symptoms have resolved. Each syringe provides one daily dose for a 500kg horse. Each division on the dial-a-dose plunger provides sufficient product to treat 50kg of bodyweight. Replace cap after use. Keep the container in the outer carton.

8. WITHDRAWAL PERIOD

Do not use in horses intended for human consumption. Treated horses may never be slaughtered for human consumption. The horse must have been declared as not intended for human consumption under national horse passport legislation.

9. SPECIAL WARNING(S), IF NECESSARY

Take care to avoid skin and eye contact. Gloves and suitable eye protection should be worn whilst handling this product. Wash hands and exposed skin after use. Sulfonamides 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. 1. Do not handle this substance if you know you are sensitive to sulphonamides. 2. If you develop symptoms following exposure such as a skin rash, you should seek medical advice and show the doctor this warning.

Do not use in known cases of hypersensitivity to the active substances or to any of the excipients. Use of the product should be based on susceptibility testing of the bacteria isolated from the animal.

If this is not possible, therapy should be based on local epidemiological information about susceptibility of the target bacteria. Do not use the same syringe to treat more than one animal unless horses are running together or in direct contact with each other on the same premises. Not recommended in horses with known hypersensitivity, severe hepatic dysfunction or cardiac arrhythmias. Drug absorption may be greater if food is withheld for a few hours prior to dosing.

Trimeiazine Paste can be safely administered during pregnancy and lactation.

10. EXPIRY DATE

Exp:

11. SPECIAL STORAGE CONDITIONS

Do not store above 25°C. Do not freeze.

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

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

13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE [*Distribution category*]

For animal treatment only.
To be supplied only on veterinary prescription.

POM-V

14. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Marketing Authorization Holder:

Vetoquinol UK Limited
Steadings Barn
Pury Hill Business Park
Nr. Alderton
Towcester
Northamptonshire
NN12 7LS

16. MARKETING AUTHORISATION NUMBER

Vm 08007/4046

17. MANUFACTURER’S BATCH NUMBER

Bn:

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE - LABEL

TRIMEZIADINE PASTE ORAL PASTE

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3. PHARMACEUTICAL FORM

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4. PACKAGE SIZE

45g.

5. TARGET SPECIES

Horses.

6. INDICATIONS

7. METHOD AND ROUTE OF ADMINISTRATION

Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Do not use in horses intended for human consumption. Treated horses may never be slaughtered for human consumption. The horse must have been declared as not being intended for human consumption under national horse passport legislation.

9. SPECIAL WARNINGS, IF NECESSARY

Sulfonamides may occasionally cause severe allergic reactions. See carton for full user warnings.

10. EXPIRY DATE

Exp:

11. SPECIAL STORAGE CONDITIONS

Do not store above 25°C. Do not freeze.

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Please read the package leaflet.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

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To be supplied only on veterinary prescription.

FOM-V

14. THE WORDS "KEEP OUT OF THE REACH AND SIGHT OF CHILDREN"

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Approved: 02 May 2018

