

**Part II**  
**SUMMARY OF PRODUCT CHARACTERISTICS**

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Trimediazine Paste Oral Paste

**2. QUALITATIVE AND QUANTITATIVE COMPOSITION**

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

**For a full list of excipients, see section 6.1**

**3. PHARMACEUTICAL FORM**

Oral paste.

**4. CLINICAL PARTICULARS**

**4.1 Target species**

Horses

**4.2 Indications for use, specifying the target species**

Indicated in the treatment of bacterial infections in horses caused by sensitive micro-organisms including:

*Escherichia coli*

*Rhodococcus (Corynebacterium) equi*

*Staphylococcus* spp.

*Streptococcus* spp.

The product may be effective in alimentary tract infections including diarrhoea; respiratory infections including pneumonia, pleurisy and strangles; wounds; septicaemia and general infections

**4.3 Contra-indications**

None

**4.4 Special warnings for each target species**

No special precautions.

**4.5 Special precautions for use**

**(i) Special precautions for use in animals**

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.

**(ii) Special precautions to be taken by the person administering the veterinary medicinal product to animals**

Avoid direct contact with skin and eyes. If contact occurs, wash affected area with copious amounts of water.

Seek medical advice if irritation persists.

Gloves should be worn whilst handling this product.

Wash hands and exposed skin after use.

**4.6 Adverse reactions (frequency and seriousness)**

No undesirable effects.

**4.7 Use during pregnancy, lactation or lay**

This product can be safely administered during pregnancy and lactation.

**4.8 Interaction with other medicinal products and other forms of interaction**

Drug absorption may be greater if food is withheld for a few hours prior to dosing.

**4.9 Amounts to be administered and administration route**

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.

**4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary**

The combination has a wide margin of safety. No treatment specified.

**4.11 Withdrawal period(s)**

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.

**5. PHARMACOLOGICAL PROPERTIES**

**ATC Vet Code:** QJ01EW10

Sulfadiazine (SDZ) inhibits the incorporation of para-aminobenzoic acid into folic acid and trimethoprim (TMP) inhibits the enzyme dihydrofolate reductase (DHFR) which converts dihydrofolic acid into tetrahydrofolic acid. (TMP) and (SDZ) act together synergistically with a double-blockage mode of action. The combination is bactericidal inhibiting sequential steps in the synthesis of purines which are required for DNA synthesis. TMP-SDZ combinations have a broad bactericidal action against many gram-positive and gram-negative aerobic bacteria, and a large proportion of anaerobic bacteria.

## **6. PHARMACEUTICAL PARTICULARS**

### **6.1 List of excipients**

Methyl hydroxybenzoate  
Propyl hydroxybenzoate  
Propylene glycol  
Carbomer  
Sodium hydroxide solution  
Purified water

### **6.2 Incompatibilities**

None known.

### **6.3 Shelf life**

Shelf-life of the veterinary medicinal product as packaged for sale: 2 years.

### **6.4 Special precautions for storage**

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

### **6.5 Nature and composition of immediate packaging**

Creamy white paste in plastic disposal dial-a-dose syringes containing 45g of product.

### **6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products**

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

## **7. MARKETING AUTHORISATION HOLDER**

Vétoquinol UK Limited  
Vetoquinol House  
Great Slade  
Buckingham Industrial Park  
Buckingham  
MK18 1PA

## **8. MARKETING AUTHORISATION NUMBER(S)**

Vm 08007/4046

## **9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

04 August 1993/04 August 2003

**10. DATE OF REVISION OF THE TEXT**  
July 2008