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

Do not use in known cases of hypersensitivity to the active substances or to any of the excipients.

4.4 Special warnings for each target species

No special precautions.

4.5 Special precautions for use

i) Special precautions for use in animals

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.

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 periods

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

Vetoquinol UK Limited
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NN12 7LS

8. MARKETING AUTHORISATION NUMBER

Vm 08007/4046

9. DATE OF FIRST AUTHORISATION

04 August 1993

10. DATE OF REVISION OF THE TEXT

May 2018

Approved: 02 May 2018