

## **SUMMARY OF PRODUCT CHARACTERISTICS**

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

Trimediazine Plain Oral Powder

### **2. QUALITATIVE AND QUANTITATIVE COMPOSITION**

#### Active substances

Trimethoprim.	5% w/w
Sulfadiazine.	25.0% w/w

For a full list of excipients, see section 6.1

### **3. PHARMACEUTICAL FORM**

Oral powder

### **4. CLINICAL PARTICULARS**

#### **4.1 Target species**

Horses.

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

Trimediazine Plain 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.

#### **4.3 Contra-indications**

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

#### **4.4 Special warnings for each target species**

The use of Trimediazine Plain in horses under 1 year old should be avoided.

#### **4.5 Special precautions for use**

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

To avoid possible crystalluria, adequate water intake is essential.

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

Persons handling this product should avoid inhalation of any dust and contact with skin. Wear either a disposable half-mask respirator conforming to European Standard to EN149 or a non-disposable respirator to European Standard to EN140 with filter EN143 when mixing or handling this product. Rubber gloves should be worn when mixing or handling this 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.

1. Do not handle this product 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.

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

None known

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

In the rat and the rabbit, trimethoprim/sulfadiazine combinations did not produce any 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 Trimediazine Plain on the development of new born foals, it would be prudent not to feed very young foals with milk obtained from mares being treated.

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

None known

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

For oral administration in the feed.

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.

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

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

#### **4.11 Withdrawal period(s)**

Meat: 6 months

### **5. PHARMACOLOGICAL PROPERTIES**

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.

ATC vet code: QJ01EW10

### **6. PHARMACEUTICAL PARTICULARS**

#### **6.1 List of excipients**

Silica colloidal anhydrous  
Glucose monohydrate

#### **6.2 Incompatibilities**

None known

#### **6.3 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.

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

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

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

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

**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  
Steadings Barn  
Pury Hill Business Park  
Nr. Alderton  
Towcester  
Northamptonshire  
NN12 7LS

**8. MARKETING AUTHORISATION NUMBER**

Vm 08007/4036

**9. DATE OF FIRST AUTHORISATION**

13 August 1992

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

May 2018

Approved: 02 May 2018

