

Part II
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

Avoid inhalation and 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. Avoid inhaling

dust from the product. The use of a mask is recommended if the product is handled regularly. Handle only in a well ventilated area.

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

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8. MARKETING AUTHORISATION NUMBER(S)

IE: VPA No. 10966/4/1
UK: VM 08007/4036

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

IE: 01 October 1988/01 October 2005
UK: 13 August 1992/13 August 2007

10. DATE OF REVISION OF THE TEXT

June 2009