

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Trimediazine BMP Premix for medicated feeding stuff

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each Kg contains:

Trimethoprim	25g
Sulfadiazine	125g

For a full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Premix for medicated feeding stuff

4. CLINICAL PARTICULARS

4.1 Target species

Pigs, chickens and turkeys.

4.2 Indications for use, specifying the target species

Pigs: for the treatment of atrophic rhinitis when associated with *Bordetella bronchiseptica* and streptococcal meningitis caused by *Streptococcus suis* type II.

Chickens and Turkeys: For use in the treatment of diseases caused by bacteria sensitive to potentiated sulphonamides including *Salmonella* and *pasteurella*.

4.3 Contra-indications

Do not administer to animals with known sulphonamide hypersensitivity.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

i. Special precautions for use in animals

Chickens and Turkeys: where appetite is depressed the inclusion rate

should be increased to achieve the correct dosage.

To avoid possible crystalluria, adequate water intake is essential. Particular care is needed with animals suffering from renal damage.

When incorporated at a rate of below 2kg per tonne of animal feed, the product must only be mixed by a manufacturer who is approved to mix at that level.

- ii. Special precautions to be taken by the person administering the veterinary medicinal product to animals

Incorporation into the feed must be performed by a suitably approved manufacturer. 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 EN 149 or a non-disposable respirator to European Standard EN 140 with a filter to EN 143 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)

Hypersensitivity to sulphonamides has been rarely reported, however this remains a potential undesirable effect. Crystalluria caused by precipitation of insoluble sulphonamide is a theoretical risk although rarely reported.

4.7 Use during pregnancy, lactation or lay

Data on the exact level below which no effects on foetal development were observed are not available. However extensive use of the product in different species over many years, have not shown adverse effects on the foetus.

When administered to lactating females, small amounts of trimethoprim and sulfadiazine are present in the maternal milk. Since no studies have been reported of the effect on the development of new born young of the ingestion of this milk, it would be prudent not to feed very young animals with milk obtained from the mother.

4.8 Interaction with other medicinal products and other forms of interaction

None known.

4.9 Amounts to be administered and administration route

Pigs: Incorporate into finished feed at the following rate according to feed intake and dosage required (combined active ingredients 15 to 30mg/kg bodyweight). Administer for 5 days.

Feed intake per day per kg bodyweight	Inclusion rate kg per tonne of feed
Up to 35g	2.75 - 5.5kg
35 - 40g	2.50 - 5.0kg
40 - 45g	2.25 - 4.5kg
45 - 50g	2.00 - 4.0kg
50 - 55g	1.75 - 3.5kg
55 - 65g	1.50 - 3.0kg

Sows: Depending on feed intake, bodyweight and dosage required incorporate to give a dosage of 15-30mg combined active ingredients per kg bodyweight.

Chickens and Turkeys: Incorporate into finished feed at 2kgs per tonne and feed for 10 days.

To ensure thorough dispersion, the product should first be mixed with 12.5kg of feed before incorporation in the final mix.

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)

Pigs – Meat: 5 days

Chickens – Meat: 1 day

Turkeys – Meat: 3 days

Do not administer to birds producing eggs intended for human consumption

5. PHARMACOLOGICAL PROPERTIES

ATC Vet Code: QJ01EW10

Pharmacodynamic properties

Sulfadiazine is a bacterial antibiotic belonging to the sulphonamide group, which acts by interference with the synthesis of nucleic acids. Trimethoprim is a dihydrofolate 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.

Pharmacokinetic properties

Following oral administration of sulfadiazine and trimethoprim to chickens, $t_{1/2\alpha}$ and $t_{1/2\beta}$ values of 0.756 and 7.07 hours (sulfadiazine) and 0.680 and 6.24 hours (trimethoprim) were obtained. Values for t_{max} were 2.46 and 2.44 hours, values for C_{max} were 86.45 and 3.65 μ g/ml and values of AUC were 620.50 and 19.87 μ g hour/ml, respectively for sulfadiazine and trimethoprim.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sorbitol Solution
Poloxyl 35 Castor Oil
Maize Oil
Dextrin
Sorbitol
Silica Colloidal Anhydrous
Calcium Carbonate

6.2 Incompatibilities

None known.

6.3 Shelf life

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

Shelf-life after incorporation into meal or pelleted feed: 6 weeks

6.4. Special precautions for storage

Store away from food drink and animal feeding stuff.
Do not store above 25°C
Store in a dry place.

6.5 Nature and composition of immediate packaging

2kg laminated sachet and 6kg, 8kg, 10kg, 12kg and 25kg tri-wall paper sacks.
Not all of these presentations are marketed.

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

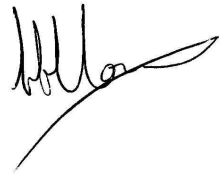
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9. DATE OF FIRST AUTHORISATION

11 August 1995

10. DATE OF REVISION OF THE TEXT

May 2018

A handwritten signature in black ink, consisting of several loops and a long, sweeping tail that curves downwards and to the right.

Approved 02 May 2018