SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Trimediazine 15% Premix for medicated feeding stuff

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Sulfadiazine	12.5% w/w
Trimethoprim	2.5% w/w
Limestone Flour to	100.0%

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

Chickens, turkeys and Pigs

4.2 Indications for use, specifying the target species

Trimediazine 15% Premix for medicated feeding stuff is indicated for use in the treatment of diseases caused by bacteria sensitive to potentiated sulphonamides.

Chickens and turkeys: For use in the treatment of diseases caused by bacteria sensitive to potentiated sulphonamides including infections due to *Salmonella* infection and pasteurellosis.

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

4.3 Contra-indications

The product should not be administered to animals with known sulphonamide hypersensitivity.

4.4 Special warnings for each target species

Not applicable

4.5 Special precautions for use

i. Special precautions for use in animals

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

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-make 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 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 has not shown adverse effects on the foetus. It is concluded that this product can be used safely in pregnant animals at the recommended dose rates.

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 effects 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

Only to be mixed with dry feed

Chickens and turkeys: Incorporate into finished feed at 2kg per tonne and feed for 10 days

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

Feed intake per day per kg bodyweight	Inclusion rate per tonne of feed	
	15mg/kg	30mg/kg
Up to 35g	2.75	5.5 kg
35 to 40g	2.50	5.0 kg
40 to 45g	2.25	4.5 kg
45 to 50g	2.00	4.0 kg
50 to 55g	1.75	3.5 kg
55 to 65g	1.50	3.0 kg

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

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

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 and offal:

Chickens	1 day
Turkeys	3 days
Pigs	7 days

Do not administer to birds producing eggs for human consumption

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic Properties

Sulfadiazine is a bacteriostatic 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.

5.2 Pharmacokinetic Properties

Following oral administration of sulfadiazine and trimethoprim to chickens, t½α and t½β values of 0.756 and 7.07 hours (sulfadiazine) and 0.680 and 6.24 hours (trimethoprim) were obtained. Values for Tmax were 2.46 and 2.44 hours, values for Cmax were 86.45 and 3.65mcg/ml and values of AUC were 620.50 and 19.87 mcg.hour/ml, respectively, for sulfadiazine and trimethoprim.

Following a single dose of Trimediazine 15% Premix for medicated feeding stuff (2kg/1000kg of food), peak plasma concentrations of sulfadiazine and trimethoprim were 3.25mcg/ml and 0.37mcg/ml, respectively. Following the same dose twice daily for 5 days, maximum peak plasma concentrations of 2.35mcg/ml sulfadiazine were attained at 3 hours and 0.43mcg/ml trimethoprim at 30 hours.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Limestone flour

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

Do not store above 25°C. Store away from animal feeding stuff in a dry place. Protect from light and moisture.

Medicated feedingstuffs: The product will remain stable in the finished feed for 6 weeks.

6.5 Nature and composition of immediate packaging

2kg powder in a metallised polyester sachet, heat sealed. Also 6kg, 8kg, 12kg and 25kg tri-wall paper sack, sealed.

6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products, if appropriate

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 08007/4023

9. DATE OF FIRST AUTHORISATION

05 April 1990

10. DATE OF REVISION OF THE TEXT

May 2018

Approved 02 May 2018