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 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 Contraindications

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 have 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 interactions

None known.

4.9 Amounts to be administered and administration route

Only to be mixed with dry feed.

Chickens and turkeys: Incorporated into finished feed at 2 kg 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.
	15 mg/kg30 mg/kg
Up to 35 g	2.75 5.5 kg
35 - 40 g	2.50 5.0 kg
40 - 45 g	2.25 4.5 kg
45 - 50 g	2.00 4.0 kg
50 - 55 g	1.75 3.5 kg
55 - 65 g	1.50 3.0 kg

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

When incorporating at a rate of below 2 kg 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 intended for human consumption.

5 PHARMACOLOGICAL or IMMUNOLOGICAL 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 particulars

Following oral administration of sulfadiazine and trimethoprim to chickens t½α and t½ß 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 mcg/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 feedingstuff (2 kg/1000 kg of food), peak plasma concentrations of sulfadiazine and trimethoprim were 3.25 mcg/ml and 0.37 mcg/ml, respectively. Following the same dose twice daily for 5 days, maximum peak plasma concentrations of 2.35 mcg/ml sulfadiazine were attained at 3 hours and 0.43 mcg/ml trimethoprim at 30 hours.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Limestone Flour

6.2 Major 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 feeding stuffs: The product will remain stable in the finished feed for 6 weeks.

6.5 Nature and composition of immediate packaging

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

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

Any unused veterinary medicinal product product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

Vetoquinol Ireland Limited
12 Northbrook Road
Ranelagh
Dublin 6
Ireland

8 MARKETING AUTHORISATION NUMBER(S)

VPA10983/058/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 01 October 1988
Date of last renewal: 30 September 2008

10 DATE OF REVISION OF THE TEXT

August 2019