

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Sulfamethoprim Premix Veterinary

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each Kg contains:

Sulfadiazine	250g
Trimethoprim	50g

For a full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Powder for feed.

4. CLINICAL PARTICULARS

4.1 Target species

Chickens, turkeys, calves (pre-ruminating) and fish.

4.2 Indications for use, specifying the target species

For the treatment of infections caused by susceptible bacteria in broiler chicken, turkeys, pre-ruminating calves and fish.

4.3 Contra-indications

Do not administer to animals with known sulphonamide hypersensitivity or to any of the other ingredients of this medication .

Do not administer to calves with functionally mature rumens.

Do not administer to animals with severe hepatic or renal impairment or with blood dyscrasias.

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.

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.

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Any suspected adverse events should be reported to the Ministry of Health according to the National Regulation by using an online form

<http://forms.gov.il/globaldata/getsequence/getsequence.aspx?formType=AdverseEffectMedic@moh.gov.il>

4.7 Use during pregnancy, lactation or lay

Not Applicable

4.8 Interaction with other medicinal products and other forms of interaction

None known.

4.9 Amounts to be administered and administration route

Chicken and turkey turkeys: 1 kg of Sulfamethoprim Premix every 1000 kg of feed. Administer for 5-7 days.

Calves: 3 kg of Sulfamethoprim Premix for every 1000 kg of feed. Administer for 7 days.

Fish: 240 grams of Sulfamethoprim Premix for every 1 ton bodyweight of fish. Administer for 7-10 days. Food intake in fish varies depending on water temperature. Dosage should be adjusted accordingly.

Method of administration: To be incorporated into feed and mixed well. 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)

Chickens – Meat: 8 day

Turkeys – Meat: 5 days

Calves – 21 days

Fish- 30 days (at 23 °C)

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

Calcium Carbonate
Sipernat 22S

6.2 Incompatibilities

None known.

6.3 Shelf life

The expiry date of the product is indicated on the packaging materials

6.4. Special precautions for storage

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

6.5 Nature and composition of immediate packaging

1kg and 3 kg bags

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

Abic Veterinary Products Ltd.
POB 489, Beit Shemesh Industrial Zone, Israel

8. MARKETING AUTHORISATION NUMBER

081-23-92209-01

9. This leaflet format has been determined by the Ministry of Health and the content has been checked and approved in 05-2019