SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Sulfamethoprim Veterinary

2. QUALITATIVE & QUANTITATIVE COMPOSITION

Active ingredients

Trimethoprim	16 mg/ml
Sulfadiazine sodium	86.4 mg/ml

For a full list of excipients see section 6.1

3. PHARMACEUTICAL FORM

Oral solution for drinking water

4. CLINICAL PARTICULARS

4.1 Target species

Chickens.

4.2 Indications for use, specifying the target species

Anti bacterial agent for infections sensitive to the product in chickens only.

4.3 Contra-indications

None.

4.4 Special warnings for each target species

None, according to available data.

4.5 Special precautions for use

i) Special precautions for use in animals

None.

ii) Special precautions to be taken by the person administering the product to animals

Persons mixing or handling this product should avoid inhalation of any dust and contact with skin. Wear either a disposable half-mask respiratory conforming to European Standard EN149 or a non-disposable respirator to EN140 with filter EN143.
Rubber gloves should be worn when mixing or handling this product.
Contaminated clothing should be removed and any splashes to the skin or eyes should be washed immediately.
Hands and exposed skin 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 reaction 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 reaction (frequency and seriousness)

Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.
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://sideeffects.health.gov.il

4.7 Use during pregnancy, lactation and 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

1-2 ml Sulfamethoprim Veterinary per liter of drinking water for 3-5 consecutive days. (1 ml of Sulfamethoprim Veterinary is intended to treat 10 kg of bodyweight.)
The contents should be dissolved in drinking water and stirred until a uniform solution is obtained.
The intake of medicated water depends on the clinical condition of the animals.
In order to obtain the correct dosage, the concentration of the active substances may have to be adjusted accordingly. In hot weather the concentration should be reduced due to increased water uptake.

4.10 Overdose (symptoms, emergency procedures, antidotes)

No treatment specified.

4.11 Withdrawal periods

Animals and birds must not be slaughtered for human consumption during treatment.
Chickens: Chickens may be slaughtered for human consumption only after 8 days from the last treatment.
Not for use in laying chickens producing eggs for human consumption.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Veterinary preparations contain the two active substances in a 1:5.4 ratio and this combination is generally effective clinically because of the relatively broad range of drug ratio over which synergism occurs.

5.2 Pharmacokinetic properties

Both active substances are absorbed well and distributed throughout the body. Excretion occurs mainly via the urine

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Saccharine sodium, Propylene glycol, Brown shade*, Purified water

* Brown shade: Carmosine F red no.3, Yellow FDC no.6, Edicol supra red, Ponceau4R.

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

Do not store above 25°C.

6.5 Nature and contents of immediate packaging

1 liter HDPE bottle

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 material derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

7. MANUFACTURER AND MARKETING AUTHORISATION HOLDER

Abic Veterinary Products Ltd. P.O.B 489, Beit Semesh, Israel

8. MARKETING AUTHORISATION NUMBER

081-05-91497

This leaflet format has been determined by the Ministry of Health and the content has been checked and approved in 5/2019