SUMMARY OF PRODUCT CHARACTERISTICS
The format of this leaflet was determined by the Ministry of Health and its contents was checked and approved by it.

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

S.C.P. 47 Veterinary

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance:
Each gram contains Sulfachloropyrazine sodium monohydrate 470mg
For list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Powder for solution for use in drinking water.
Off-white to cream powder.

4. CLINICAL PARTICULARS

4.1 Target species

Chickens

4.2 Indications for use, specifying the target species

Prevention and treatment of coccidiosis, salmonellosis, fowl cholera in chicken.

4.3 Contraindications

Not for use in laying hens or breeders whose eggs are intended for human consumption.
Do not use in cases of hypersensitivity to the active substance or to the excipient.

4.4 Special precautions for use

Special precautions for use in animals
Use of the product should be based on susceptibility testing of the bacteria isolated from the animal. If this is not possible, therapy should be based on local (regional, farm level) epidemiological information about susceptibility of the target bacteria
If there is no significant improvement after 3 days, a new sensitivity test or a change of therapy is indicated.
After the end of the treatment, the feeding facility must be thoroughly cleaned in a suitable manner in order to remove residual amounts of the antibiotic used.
The intake of the medication depends on the clinical condition of the animals. In order to obtain the correct dosage the concentration of has to be adjusted accordingly.

Avoid overdosing. Water consumption increases at high temperatures.
Avoid underdosing. Water consumption decreases in sick animals.

Special precautions to be taken by the person administering the veterinary medicinal product to animals
When handling S.C.P. 47 Veterinary avoid direct contact with skin and mucous membranes. Wear protective equipment consisting of protective clothing, gloves, respiratory protection and protective goggles.
Do not smoke, eat or drink while handling.

4.5 Adverse reactions (frequency and seriousness)

Hypersensitivity reactions may be observed.
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

4.6 Use during pregnancy, lactation or lay

Growth, laying performance and hatching rate are not affected by the recommended dosages of S.C.P. 47 Veterinary.
Not for use in laying hens or breeders whose eggs are intended for human consumption.

4.7 Interaction with other medicinal products and others forms of interaction

None known.

4.8 Amounts to be administered and administration route

64 grams per 100 litres of drinking water for 3 consecutive days. In severe cases may be used for an additional 3 days at half the dosage. If necessary, repeat the treatment after a 2-day break.

S.C.P. 47 Veterinary is administered in drinking water; all other drinking opportunities must be turned off during the treatment period.
Medicated drinking water must be freshly prepared daily and administered immediately after S.C.P. 47 Veterinary is dissolved. The feeding is kept unchanged.

4.9 Withdrawal periods

Chickens: 4 days prior to slaughter

5. PHARMACOLOGICAL PROPERTIES

ATCvet code: QP51AG04

5.1 Pharmacodynamic properties

S.C.P. 47 Veterinary acts quickly and has a broad spectrum. S.C.P. 47 Veterinary has a bacteriostatic and antiprotozoal effect through selective inhibition of folic acid synthesis. This has the effect that the purine and consequently the DNA and RNA synthesis is suppressed. It intervenes in the development cycle of coccidia and bacteria and prevents them from multiplying. Sulfaclozin is effective in vitro and in vivo against Eimeria spp., Salmonella gallinarum and Pasteurella multocida. Resistance to sulfonamides is primarily linked to plasmids. In P. multocida, Salmonella spp. and Eimeria spp., cross-resistance to other sulfonamides is described. Sulphonamides are not effective against mycoplasma. S.C.P. 47 Veterinary does not adversely affect feed utilization, laying performance or egg shell quality.

5.2 Pharmacokinetic particulars

After oral administration, sulfaclozin is rapidly absorbed (Tm_{ax} 4 - 8 h) and the steady state plasma concentration is quickly reached (Cm_{ax} 165 - 170 µg/ml). Even with long-term treatment, sulfaclozin is not accumulated but rather quickly excreted. Only a small fraction (<0.2%) of acetylated and biologically inactive sulfaclosin is found in plasma and tissue. The average half-life is between 12 and 20 hours.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Dextrose

6.2 Major incompatibilities

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

6.3 Shelf life

The expiry date of the product is indicated on the packaging materials.
A fresh solution should be prepared daily and used immediately after preparation.

6.4 Special precautions for storage

Store below 25ºC
Keep S.C.P. 47 Veterinary out of the reach of children.

6.5 Nature and composition of immediate packaging

320 g and 1kg

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 product 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

072-14-91672

9. DATE OF REVISION OF THE TEXT

December 2021