SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

DIAZIVET 20 VETERINARY oral solution,, for use in drinking water for broiler chickens.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

1 ml of solution contains:

Active substances:
sulfadiazine.....200 mg
trimethoprim.....40 mg

Excipients:
sodium formaldehyde sulfoxylate.....2 mg
other excipients and purified water q.s. to.....1 ml

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Solution for use in the drinking water

4. CLINICAL PARTICULARS

4.1. Target species

Broiler chickens.

4.2. Indications for use, specifying the target species

In broilers - Treatment of bacterial infections of the respiratory and gastrointstinal tract, due to microorganisms sensitive to the combination of sulphadiazine and trimethoprim. Coccidiosis in broilers.

4.3. Contraindications

Do not administer to animals with known hypersensitivity to the sulphonamides or with severely impaired hepatic or renal function.

4.4. Special warnings for each target species

Administer just the minimum dosages under climatic conditions which increase water consumption. In cases of prolonged therapy (anticoccidial therapy) administration of vitamin K is recommended.

4.5. Special precautions for use

Special precautions for use in animals

Do not administer in acidic waters.
Use of the product should be based on sensitivity testing against bacteria isolated from the animals to be treated. If this should not be possible, therapy should be based on local epidemiological information (regional or from breeding establishments). Improper use of the product may increase the prevalence of bacteria resistant to potentiated sulphonamides and may decrease the efficacy of treatment with other categories of antimicrobial agents, owing to possible cross-resistance.

Special precautions to be taken by the person administering the veterinary medicinal product to the animals

People with known hypersensitivity to the sulphonamides should avoid contact with the veterinary medicinal product.
Adopting the usual procedures for preparation or administration of the products, no special precautions for the person administering the product are necessary, although it is good practice to use protective clothing, gloves and mask to handle the product. Avoid contact with the skin and with the eyes. In cases of contact, rinse with plenty of soap and water.
Do not eat, drink or smoke whilst handling the product; wash the hands after use.

4.6. Adverse reactions (frequency and seriousness)

Allergic reactions may occur in particularly sensitive subjects.
Cases of crystalluria, haematuria and chronic toxicity phenomena, such as thrombocytopenia and leukopenia, have been reported. Prolonged oral administration can lead to a vitamin K deficiency; changes to the digestion of cellulose, to the fermentation of carbohydrates and inappetence are also described.

Reporting of suspected adverse reactions
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: /https://sideeffects.health.gov.il

4.7. Use during pregnancy, lactation or lay

Do not administer to layer hens producing eggs intended for human consumption.

4.8. Interaction with other medicinal products and other forms of interaction

Avoid concurrent use with other veterinary medicinal products with a high binding affinity to plasma proteins.

4.9. Amounts to be administered and administration route

Broiler chickens: 0.2-0.3 ml of solution per kg of body weight (equivalent to 0.7-1.0 ml per litre of drinking water and 48-72 mg of the combination per kg of body weight).

Approximate duration of treatment: 3-5 days.

In case of coccidiosis, perform two 3- day treatments with an interval of 2 days between treatments.

Administration in the drinking water must be carried out taking into account the daily consumption, which depends on the clinical condition of the animals.
To ensure the correct dosage and to avoid over- or underdosing, group the animals to be treated on the basis of body weight, taking into account the daily water consumption and carefully calculate the dosage of product to be diluted in the drinking water.

4.10. Overdose (symptoms, emergency procedures, antidotes), if necessary

Administrations at doses greater than those indicated are generally well tolerated.

4.11. Withdrawal periods

Meats and offal
Broiler chickens: 8 days.
Use is not permitted in layer hens producing eggs intended for human consumption.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: combinations of sulphonamides and trimethoprim, including derivatives
ATC Vet Code: QJ01EW10

5.1. Pharmacodynamic properties

Sulfadiazine and trimethoprim block, at two different and subsequent stages, folic acid synthesis, which is indispensable for the development of bacteria. The effect of this double sequential suppression is a broad-spectrum bactericidal action (Gram-positive and Gram-negative bacteria and certain protozoa), also including microorganisms which are not very sensitive or resistant to one or other of the two components.

The combination, in addition to potentiating the chemotherapeutic activity, allows to obtain a therapeutic effect at lower dosages compared to the use of the individual active substances.

5.2. Pharmacokinetic particulars

After oral administration in the drinking water at the recommended doses, efficacious levels of the of the sulfadiazine-trimethoprim combination are detectable in all the principal tissues and fluids in the organism, for the entire duration of treatment. The highest tissue concentrations of the active substances are already seen one hour after administration by the oral route.

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients

ethanolamine
lactic acid
n-methyl-2-pyrrolidone
polyethylene glycol 400 (Macrogol 400)
sodium hydroxide
sodium formaldehyde sulfoxylate
purified water

6.2. Incompatibilities

Do not mix with other veterinary medicinal products.

6.3. Shelf-life

The expiry date of the product is indicated on the packaging materials Shelf-life after first opening the immediate packaging: 3 months.
Shelf-life after dilution according to directions: 24 hours.

6.4. Special precautions for storage

Store the product below 25ºC. Protect from light.

6.5. Nature and composition of immediate packaging

- 1 litre high density polyethylene bottle with aluminium and HDPE screw-cap.

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 medicinal products should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

Manufactuer: FATRO S.p.A. - Via Emilia, 285 - Ozzano Emilia (Bologna), Italy.
Registration holder: Romat LTD., HA'MAAPILIM 39/104 , HERZLIYA 46543

8. Registration number: 083-11-92352-00

Approved on: July 2020