Consumer leaflet for a Veterinary Product

This medicine is marketed according to a veterinarian's prescription only

For use in animals only

1. NAME OF THE VETERINARY MEDICINAL PRODUCT, form and strength

DIAZIVET 20 VETERINARY

Solution for drinking water

2. Active substances and quantity in unit dose

SULPHADIAZINE 20 G/100 ML
TRIMETHOPRIM 4 G/100 ML

For a list of excipients in the product, see section 13 "additional information"

3. What is the medicine used for

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

Therapeutic group:
SULPHADIAZINE: Sulphonamide antibiotic
TRIMETHOPRIM: bacteriostatic antibiotic

4. Contraindications

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

5. Adverse reactions

Allergic reactions may occur in particularly sensitive subjects.
Cases of crystalluria, haematuria and chronic toxicity phenomena, such as thrombocytopenia (low levels of platelets) and leukopenia (reduced number of white blood cells), 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
Side effects can be reported to the Ministry of Health by clicking on the link "Adverse Drug Reactions Repot" that appears on the home page of the Ministry of Health web site (www.health.gov.il), which leads to an online form for reporting side effects.
Alternatively you can use the following link:
https://sideeffects.health.gov.il

6. Target animals: Broilers

7. Dosage and administration:

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).

Duration of treatment: 3-5 days .

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

8. How to use the product

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.

9. Withdrawal period
Broilers: 8 days
Not for use in layer hens producing eggs intended for human consumption.

10. Warnings

- 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.

- **Special precautions for use in target 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.
  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.
  It is recommended 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.
  Laboratory studies in rabbits and rats with the excipient N-methyl pyrrolidone have shown evidence of foetotoxic effects. The veterinary medicinal product should not be administered by pregnant women and women suspected of being pregnant. Personal protective equipment consisting of gloves should be worn when handling the veterinary medicinal product by women of childbearing age.

- **Use during lay**
  Not for use in layer hens producing eggs intended for human consumption.

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

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

- **Incompatibility**
  Do not mix with other veterinary medicinal products.

11. Storage directions

- Avoid poisoning! This medicine and any other medicine should be kept in a closed place out of the reach of children and/or infants in order to avoid poisoning.
- Do not use the medicine after the expiry date (exp. date) appearing on the package. The expiry date refers to the last day of that month.
- Storage conditions: in a dark place, below 25°C.
- Shelf-life after first opening the immediate packaging: 3 months when stored below 25°C.
- Shelf-life after dilution according to directions: 24 hours when stored below 25°C.

12. Directions for disposal of the product/ product remainders at the end of use

Any unused veterinary medicinal product or waste materials derived from such medicinal products should be disposed of as toxic waste, do not throw to sewage.

13. Additional information

- In addition to the active ingredients, the medicine also contains:
  1 ml of solution contains the excipients:
  N-methyl pyrrolidone…….300 mg
  sodium formaldehyde sulfoxylate.....2 mg
  other excipients and purified water q.s. to.....1 ml

  Full list of excipients:
  Polyethylene glycol 400 (Macrogol 400), Purified water, N-Methyl Pyrrolidone, Sodium hydroxide, Ethanolamine, Lactic acid, Sodium formaldehyde sulfoxylate.

- Appearance of the medicine and content of package: clear yellow solution.
- Size of pack: 1 Litre
- Registration holder: Romat LTD., HA'MAAPILIM 39/104 , HERZLIYA 46543
- Manufacturer: FATRO S.p.A., Via Emilia, 285 -40064, Ozzano Emilia, Bologna, Italy.

Revised in June 2024.

Registration number in the national Ministry of Health registry:
083-11-92352-00