

Veterinary medicine package leaflet

This medicine is marketed according to a veterinarian's prescription only
For use in animals only

1. Name, form, and strength of the veterinary medicine

Soludox 50% Veterinary, powder for solution for use in drinking water

2. Name and quantity of active ingredients in a unit dose

Doxycycline hyclate 50%

For the list of inactive ingredients, see section 13.

3. What is this medicine intended for?

Treatment of respiratory infections caused by micro-organisms sensitive to doxycycline in pigs and broilers.

Therapeutic group: antibiotic of the Tetracyclines group.

4. Contraindications

Do not use in cases of hypersensitivity to the active substance or to any of the excipients of this product.
Do not use in animals with an impaired liver function.

5. Side effects

Tetracyclines may - in very rare cases - induce photosensitivity and allergic reactions. If suspected adverse reactions occur, treatment should be discontinued. Inform your veterinarian if adverse reactions occur that are not mentioned in this leaflet.

Side effects can be reported to the Ministry of Health by clicking on the link 'Adverse Drug Reactions Report' 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

Pigs, broilers.

7. Dosage and administration

Administration in drinking water.

The recommended dose in pigs is:

12.5 mg doxycycline hyclate (25 mg product) per kg body weight per day for 4 consecutive days. If no improvement in clinical signs is seen within this time, the diagnosis should be reviewed and treatment changed. In case of severe infections the medication period may be prolonged for a maximum of 8 consecutive days as determined by the attending veterinarian.

The recommended dose in broiler chickens is:

10 mg doxycycline hyclate (20 mg product) per kg body weight per day for 3-4 consecutive days in case of infections caused by *P. multocida* and
20 mg doxycycline hyclate (40 mg product) per kg body weight per day for 3-4 consecutive days in case of infections caused by *O. rhinotracheale*.

Based on the dose to be used, and the number and weight of the animals to be treated, the daily amount of product required can be calculated. The following formula can be used to calculate the concentration of the product required in drinking water:

$$\frac{\text{mg product / kg body weight}}{\text{/ day}} \times \frac{\text{Mean body weight (kg)}}{\text{of animals to be treated}} = \dots \text{ mg product per Liter of drinking water}$$

Mean daily water consumption (liter) per animal

To ensure a correct dosage body weight should be determined as accurately as possible. The uptake of medicated drinking water depends on the clinical condition of the pigs/chickens. In order to obtain the correct dosage the concentration of doxycycline has to be adjusted accordingly. The use of suitably calibrated weighing equipment is recommended if part packs are used. The daily amount of product required is to be added to the drinking water such that all medication will be consumed in 24 hours. Medicated drinking water should be replaced every 24 hours. It is recommended to prepare a concentrated pre-solution - approximately 100 grams product per liter drinking water - and to dilute this further to therapeutic concentrations if required. Alternatively, the concentrated solution can be used in a proportional water medicator. Solubility of the product is pH dependent and it may precipitate out if it is mixed in hard alkaline drinking water. Use at minimum concentrations of 200 mg powder per liter drinking water in areas with hard alkaline drinking water (hardness above 10.2 °d and pH more than 8.1). During the treatment period animals should not have access to water sources other than the medicated water.

8. How to use the product

Administration in drinking water, according to the instructions in section 7.

9. Withdrawal period -

Pigs:

Meat and offal: 4 days.

Broilers:

Meat and offal:

- 3 days, following a dose rate of 10 mg/kg body weight for 4 days
- 9 days, following a dose rate of 20 mg/kg body weight for 4 days.

Not to be administered to hens producing eggs for human consumption.

Do not use within 4 weeks of onset of laying.

10. Warnings

- Special warnings about the safety of using this medicine in animals

Due to likely variability (time, geographical) in susceptibility of bacteria to doxycycline, especially susceptibility of *A. pleuropneumoniae* and *O. rhinotracheale* which may differ from country to country and even farm to farm, bacteriological sampling and susceptibility testing are recommended. Use of the product should be based on the culture and sensitivity of micro-organisms from diseased cases on farms. If this is not possible, therapy should be based on local (regional, farm level) epidemiological information about susceptibility of the target bacteria.

As eradication of the target pathogens may not be achieved, medication should therefore be combined with good management practices, e.g. good hygiene, proper ventilation, no overstocking.

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

If you know you are allergic to the tetracycline class of antibiotics, special care should be taken when handling this product or the medicated solution.

During preparation and administration of the medicated drinking water, skin contact with the product and inhalation of dust particles should be avoided. Wear impermeable gloves (e.g. rubber or latex) and an

appropriate dust mask (e.g. disposable half-mask respirator conforming to European Standard EN149) when applying the product.

In the event of eye or skin contact, rinse the affected area with large amounts of clean water and if irritation occurs, seek medical attention. Wash hands and contaminated skin immediately after handling the product.

If you develop symptoms following exposure such as skin rash, you should seek medical advice and show this warning to the physician. Swelling of the face, lips or eyes, or difficulty with breathing are more serious symptoms and require urgent medical attention.

Do not smoke, eat or drink while handling the product.

Take measures to avoid producing dust when incorporating the product into water. Avoid direct contact with skin and eyes when handling the product to prevent sensitisation and contact dermatitis.

- Use during pregnancy, lactation or lay

Doxycycline has a low affinity for forming complexes with calcium and studies have demonstrated that doxycycline scarcely affects skeleton formation. No negative effects were observed in poultry after the administration of therapeutic doses of doxycycline.

In the absence of specific studies the use of the product is not recommended during pregnancy or lactation.

Not for use in hens producing eggs for human consumption.

- Interaction with other medicinal products and other forms of interaction

Do not combine with antibiotics that are bactericidal, e.g. penicillins or cephalosporins.

Absorption of doxycycline can be decreased in the presence of high quantities of calcium, iron, magnesium or aluminium in the diet. Do not administer together with antacids, kaolin and iron preparations.

It is advised that the interval between the administration of other products containing polyvalent cations should be 1-2 hours because they limit the absorption of tetracyclines.

Doxycycline increases the action of anticoagulants.

The solubility of the product is pH dependent and it will precipitate if mixed in alkaline solution.

Do not store the drinking water in metallic containers.

- Overdose:

Overdoses up to 1.6 times the label recommended dose resulted in no clinical signs that could be attributed to treatment. Poultry tolerate double overdoses of doxycycline (40 mg/kg body weight) without any clinical effect.

- Incompatibility:

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

11. Storage instructions

- Prevent poisoning! To prevent poisoning, keep this, and all other medicines, in a closed place out of reach of children and/or infants.

- Do not use the medicine after the expiry date (exp. date) stated on the package. The expiry date refers to the last day of that month.

- Storage conditions: Store below 25°C.

- Shelf life after first opening the immediate packaging: 9 months.

- Shelf life after dilution or reconstitution according to directions: 24 hours.

- Keep the bag tightly closed after first opening in order to protect from moisture.

12. Instructions for disposal of the product / any remaining product after use

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of as toxic waste, do not dispose of via wastewater.

13. Additional information

- In addition to the active ingredients, this medicine also contains Tartaric acid.

- What the medicine looks like and what the package contains: yellow powder.
- Pack sizes: bag containing 100 g, 250 g, 500 g, 1000 g. Not all pack sizes may be marketed.

Manufacturer: EUROVET ANIMAL HEALTH B.V., HANDELSWEG 25, 5530 AD BLADEL,
NETHERLANDS

License holder: Vetmarket Ltd., 23 HACHORESH WAY, INDUSTRIAL PARK
MODI'IN REGION, Shoham.

Approved in 4/2022

**Registration number of the medicine in the Ministry of Health National Drug Registry:
082-73-92322**