

CONSUMER PACKAGE LEAFLET FOR VETERINARY MEDICINAL PRODUCT

The medicine is dispensed with a veterinarian's prescription only
For animal use only

1. NAME OF THE MEDICINAL PRODUCT:

Exzolt Veterinary

Solution for use in drinking water

2. COMPOSITION:

Each 1 ml contains:

Active substance:

Fluralaner 10 mg

The list of excipients is detailed in section 13 – “Additional information”.

3. WHAT IS THE MEDICINAL PRODUCT INTENDED FOR:

Treatment of poultry red mite (*Dermanyssus gallinae*) infestation in pullets, breeders and layer hens.

Therapeutic group: ectoparasiticides for systemic use

4. CONTRAINDICATIONS:

Do not use the product in case of known sensitivity to Fluralaner or to any of the additional ingredients of the medicine.

5. SIDE EFFECTS:

None known.

If you notice any side effects, even those not already listed in this package leaflet or you think that the medicine has not worked, please inform your veterinary surgeon.

Side effects can be reported to the Ministry of Health by clicking on the link “Reporting Side Effects due to Drug Treatment” found on the Ministry of Health homepage (www.health.gov.il), that directs you to the online form for reporting side effects, or by entering the link:

<https://sideeffects.health.gov.il/>

6. TARGET ANIMALS:

Chickens (pullets, breeders and layer hens).

7. METHOD OF ADMINISTRATION AND DOSAGE:

For use in drinking water.

The dose is 0.5 mg fluralaner per kg body weight (equivalent to 0.05 ml of solution) administered twice, 7 days apart. The complete course of treatment must be administered for a full therapeutic effect. If another course of treatment is indicated, the interval between two courses of treatment should be at least 3 months.

8. HOW TO USE THE PRODUCT:

Determine the duration of time (between 4 and 24 hours) over which to administer the medicated water on the treatment day. This period of time must be long enough to allow all the birds to receive the required dose. Estimate how much water birds will consume during treatment based on the previous day's water consumption. The product should be added to a volume of water that the chickens will consume in one day. No other source of drinking water should be available during the treatment period.

Calculate the volume of product needed based on the total weight of all birds in the house to be treated. To ensure administration of the correct dose, the body weight should be determined as accurately as possible and an accurate measuring device should be used for measuring the calculated volume of the product to be administered.

The required volume of product for each treatment day is calculated from the total body weight (kg) of the entire group of chickens to be treated:

$$\text{Volume of product (ml) per treatment day} = \text{Total body weight (kg) of chickens to be treated} \times 0.05 \text{ ml/kg}$$

Therefore 500 ml of product treats 10,000 kg body weight (e.g., 5,000 chickens of 2 kg body weight each) per day of treatment administration.

The instructions below need to be followed, in the order described, to prepare the medicated water:

- Check the water system to ensure it works properly and is free of leaks; also ensure that water is available to all nipple or bell drinkers.
- For each day of treatment, medicated water must be freshly prepared.
 - Mix the required volume of the product with water into a large medication tank or create a stock solution in a small container. The stock solution must be further diluted with drinking water and administered over time, using a dosing pump. Always add product and water simultaneously in order to avoid foaming. It is important to rinse the measuring device used to measure the required product volume during the filling phase in order to ensure that the complete dose is emptied into the medication tank or the stock solution and that no residues remain in the measuring device. Stir the stock solution or the content of the medication tank gently until the medicated water is homogeneous. Connect the medication tank or the dosing pump to the drinking water system.

- Make sure the dosing pump is properly set to deliver the medicated water during the predetermined treatment period (hours).
- Prime the drinker lines with medicated water and check to see when medicated water has reached the end of the line. This procedure should be repeated on each day of administration.

After each treatment administration, fill the stock solution container with clean (unmedicated) water to rinse the water lines.

9. WITHDRAWAL PERIOD:

Meat and offal: 14 days.

Eggs: zero days.

10. WARNINGS:

Special warnings regarding the use of medicine during treatment in target animal

The following practices should be avoided because they increase the risk of development of resistance and could ultimately result in ineffective therapy:

- too frequent and repeated use of acaricides (pesticides of the Acari family) from the same class, over an extended period of time
- underdosing, which may be due to underestimation of body weight, misadministration of the product, or lack of calibration of the volume measuring device.

Special warnings regarding the safety of use of medicine in animals

Strict biosecurity measures at house and farm level should be implemented to prevent re-infestation of treated houses. To ensure long term control of the mite populations in a treated house, it is essential to treat any other infested poultry in houses in proximity to the treated one.

Special warnings regarding the safety of the person administering the medicinal product

The veterinary medical product may be slightly irritating to skin and/or eyes.

Avoid contact with skin, eyes and mucous membranes.

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

Wash hands and contacted skin with soap and water after use of the product.

In case of eye contact, immediately rinse thoroughly with water.

If the product is spilled, remove any affected clothes.

Additional warnings

Exzolt Veterinary should not enter water courses as this may be dangerous for aquatic invertebrates.

Fertility and lay

The safety of the veterinary medicinal product has been demonstrated in layers and breeders. The product can be used during lay.

Overdose

Safety was demonstrated in 3-week-old and adult chickens treated with overdoses of up to 5 times the recommended dose for 3 times the recommended duration of treatment.

No negative effects on egg production were observed when layer hens were treated with overdoses of up to 5 times the recommended dose for 3 times the recommended duration of treatment.

There were no adverse effects on reproductive performance when breeding chickens were treated with overdoses of 3 times the recommended dose for twice the recommended duration of treatment.

Incompatibility

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

11. STORAGE INSTRUCTIONS:

- Avoid poisoning! This medicinal product and any other medicinal product, should be kept in a closed place, out of the reach and sight of children and/or infants in order to protect from poisoning.
- Do not use the medicinal product after the expiry date (exp. Date) appearing on the package. The expiry date refers to the last day of that month.
- Storage conditions: Store below 30°C.
- Shelf life after first opening the container: 1 year.
- Shelf life after dilution according to directions: 24 hours.

12. INSTRUCTIONS REGARDING DISPOSAL OF THE MEDICINAL PRODUCT/REMNANTS OF THE MEDICINAL PRODUCT AFTER USE:

Exzolt Veterinary should not enter water courses as this may be dangerous for aquatic invertebrates.

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

13. ADDITIONAL INFORMATION:

- In addition to the active substance(s), the medicine also contains:
Polysorbate 80
Diethylene glycol monoethyl ether
Alpha-tocopherol
- What the medicine looks like: Light yellow to dark yellow solution.
- The package: bottle of 1 litre or 4 litres. Not all pack sizes may be marketed.

- Environmental properties:
Fluralaner has been shown to be very persistent in soil under both, aerobic and anaerobic conditions.
Fluralaner degrades in aquatic sediment under anaerobic conditions while it has been shown to be very persistent under aerobic conditions.
- **Registration holder and address:** Intervet Israel Ltd., Industrial Park Neve Ne'eman, Hod Hasharon 45240.
- **Manufacturer name and address:**
Intervet Productions S.A., Rue de Lyons, 27460 Igoville, France.

Revised in March 2022 according to MOHs guidelines.

Registration number of the medicinal product in the National Drug Registry of the Ministry of Health: 163-52-35407-00