

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Exzolt 10 mg/ml solution for use in drinking water for chickens

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance:

10 mg fluralaner

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Solution for use in drinking water.
Light yellow to dark yellow solution.

4. CLINICAL PARTICULARS

4.1 Target species

Chickens (pullets, chickens for reproduction and layer hens).

4.2 Indications for use, specifying the target species

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

4.3 Contraindications

None.

4.4 Special warnings for each target species

Unnecessary use of antiparasitics or use deviating from the instructions given may increase the resistance selection pressure and lead to reduced efficacy. The decision to use the product should be based on confirmation of the parasitic species and burden, or of the risk of infestation based on its epidemiological features for each flock.

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 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.

4.5 Special precautions for use

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

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.

Special precautions for the protection of the environment:

Medicated drinking water should not enter surface waters.

4.6 Adverse reactions (frequency and seriousness)

None known.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See also the last section of the package leaflet for respective contact details.

4.7 Use during pregnancy, lactation or lay

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

4.8 Interaction with other medicinal products and other forms of interaction

None known.

4.9 Amounts to be administered and administration route

For use in drinking water.

The dose is 0.5 mg fluralaner per kg body weight (equivalent to 0.05 ml of product) 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.

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 medication 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:

Volume of product (ml) per treatment day = Total body weight (kg) of chickens to be treated x 0.05 ml/kg

Therefore:

- 500 ml of product treats 10,000 kg body weight (e.g., 5,000 chickens of 2 kg body weight each).
- or 1 ml of product treats 20 kg body weight (e.g., 10 chickens of 2 kg body weight each).

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

For large poultry farms using 1-litre or 4-litre bottles of the veterinary medicinal product:

- 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 proportioner or 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 proportioner or 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.

For small poultry farms using 4-ml or 50-ml bottles of the veterinary medicinal product:

- Check that the water system functions properly and is free of leaks.
- For each day of treatment, medicated water must be freshly prepared.
 - Mix the required volume of the product with the determined amount of water in a measuring device.
 - Add product and water simultaneously in order to avoid foaming.
 - Stir stock solution gently but thoroughly until the medicated water is homogeneous.
 - It is important to rinse the measuring device to ensure that the complete dose is provided to the chickens and that no residues remain. Add the rinse water to the drinkers.
 - Ensure that medicated water is evenly divided to all drinkers.
- At time of initial use, remove the original cap from the bottle and discard it. Twist on the in-use cap provided in the carton box. Doing so will permanently insert the syringe adaptor into the neck of the bottle.
- To dose:
 - Remove the in-use cap.
 - Attach a 1-ml dosing syringe to the bottle by gently pushing the end of the syringe into the syringe adaptor.
 - Turn the bottle/syringe upside down. Pull down on the plunger to withdraw the correct dose volume. If any air bubbles are seen in the syringe, push them out and pull down again on the plunger until the correct volume is withdrawn.
 - Turn the bottle/syringe upright. Remove the syringe from the syringe adaptor.
 - Replace the in-use cap.
 - Administer the dose in the drinking water.

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

No adverse reactions were observed following the treatment of 3-week old and adult chickens dosed with 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 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 3 times the recommended dose for twice the recommended duration of treatment.

4.11 Withdrawal period(s)

Meat and offal: 14 days.

Eggs: zero days.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Antiparasitic products, ectoparasiticides for systemic use, isoxazolines.

ATCvet code: QP53BE02.

5.1 Pharmacodynamic properties

Fluralaner is an acaricide and an insecticide which has a high potency against poultry mites, mostly by exposure via feeding, i.e. it is systemically active against the target parasites.

Fluralaner is a potent inhibitor of parts of the arthropod nervous system by acting antagonistically on ligand-gated chloride channels (GABA-receptor and glutamate-receptor). In molecular on-target studies on insect gamma-aminobutyric acid (GABA) receptors of flea and fly, dieldrin resistance does not affect fluralaner.

The onset of activity against *Dermanyssus gallinae* is within four hours of the mites starting to feed on treated chickens.

The treatment kills mites feeding on treated chickens and stops egg production from female mites for 15 days after the first administration of the product. This activity breaks the mite life cycle.

In vitro bio-assays show that fluralaner is effective against parasites having proven field resistance, including organophosphates, pyrethroids and carbamates.

As demonstrated in a multi-site EU field study performed in commercial egg production farms, elimination of mites from infested chickens following treatment is associated with a statistically significant improvement in behavioural parameters indicative of animal welfare (reduction of night-time activity and head scratching, head shaking and preening of own plumage at night and during day-time) as well as a reduction of blood corticosterone concentration.

5.2 Pharmacokinetic particulars

After oral administration, fluralaner is absorbed rapidly from the medicated drinking water, reaching maximum plasma concentrations 36 hours after the first dose and 12 hours after the second dose. The bioavailability is high, with approximately 91% of the dose absorbed following oral administration. Fluralaner is highly bound to protein. Fluralaner is widely distributed throughout the body, with the highest concentrations reported in the liver and skin/fat. No significant metabolites are observed in chickens, and fluralaner is mainly eliminated via the hepatic route. The apparent elimination half-life is approximately 5 days following oral administration.

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.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Alpha-tocopherol (*all-rac-alpha*-tocopherol)
Diethylene glycol monoethyl ether
Polysorbate 80

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

Shelf life of the veterinary medicinal product as packaged for sale: 3 years.
Shelf life after first opening the immediate packaging: 1 year
Shelf life of the medicated drinking water: 24 hours.

6.4 Special precautions for storage

50 ml, 1 litre and 4 litre bottles:

This veterinary medicinal product does not require any special storage conditions.

4ml bottle:

After first opening of the 4 ml bottle, do not store above 30°C and, store in an upright position and use within 6 months.

6.5 Nature and composition of immediate packaging

Colourless high density polyethylene (HDPE) bottle closed with an aluminium/polyester foil seal and a blue child-resistant polypropylene screw cap (1 litre and 4 litre presentations) or, type III amber glass bottle with a white polypropylene/polyethylene (PP/PE) child proof screw cap with expanded low density PE/aluminium foil/ PE faced liner (50 ml presentation) or, type III amber glass bottle with a white polyethylene (PE) child-proof screw cap with aluminium foil/PE/aluminium foil liner provided with four 1-ml syringes and a white polyethylene (PE) child-proof screw cap with PE press-in-bottle adapter (PIBA) (4 ml presentation).

Pack sizes: bottles of 4 ml, 50 ml, 1 litre or 4 litres.

Not all pack sizes may be marketed.

6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

Medicines should not be disposed via wastewater.

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

The veterinary medicinal product should not enter water courses as this may be dangerous for aquatic invertebrates.

7. MARKETING AUTHORISATION HOLDER

MSD Animal Health UK Limited
Walton Manor, Walton
Milton Keynes
Buckinghamshire
MK7 7AJ

8. MARKETING AUTHORISATION NUMBER

Vm 01708/5036

9. DATE OF FIRST AUTHORISATION

18 August 2017

10. DATE OF REVISION OF THE TEXT

September 2023

11. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Find more product information by searching for the 'Product Information Database' or 'PID' on www.gov.uk.

Approved 07 September 2023

A handwritten signature in black ink, appearing to read "A. Hunter." The signature is stylized with a large initial "A" and a cursive "Hunter." followed by a period.