PRODUCT BULLETIN



EXZOLT®

(fluralaner oral solution)

10 mg of fluralaner/mL

A BACKYARD BREAKTHROUGH

Simple, effective control of Northern Fowl Mites for your flock

From fresh eggs to daily entertainment, your chickens quickly become part of your life. While their personalities are easy to see, issues like Northern Fowl Mites (*Ornithonyssus sylviarum*) can be missed.

Exzolt is a proven solution that works from the inside out, delivering fast, effective control of Northern Fowl Mites through your chickens' drinking water. Now available in a 4 mL size, it makes treatment simple and practical for your flock.

PROVEN AND EFFECTIVE

- Starts reducing mites quickly with demonstrated 99%+ efficacy*
- More effective, targeted and consistent than mite sprays or homeopathic remedies
- Powered by fluralaner, a proven formulation now available for smaller flocks

SAFE FOR YOUR BIRDS

- Safe for laying hens with no egg withdrawal period
- Added to drinking water, eliminating the need for chemical sprays or dusts
- Stress-free application with no bird handling or direct contact needed

EASY TO ADMINISTER

- Ready-to-use solution added directly to drinking water
- Avoids exposure to chemical sprays or dust around your family and pets
- Two doses, seven days apart, helps break the Northern Fowl Mite life cycle



Bring the backyard breakthrough to your flock with Exzolt. Learn more at ExzoltBackyard.com.

IMPORTANT SAFETY INFORMATION: EXZOLT® (fluralaner oral solution)
Not for use in humans. Keep this and all drugs out of the reach of children. Accidental exposure may cause skin and eye irritation. Accidental ingestion may cause gastrointestinal disturbances and hypersensitivity reactions in humans. Chickens must not be slaughtered for human consumption for 11 days after the last treatment. No egg discard is required when used according to the labeling. For complete safety information and product dosing instructions, refer to the product label.

*Data on file, Merck Animal Health

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Animal Health



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For oral administration via drinking water

Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian.

Description: Exzolt (fluralaner oral solution) is a concentrate for oral administration via drinking water containing fluralaner. Each mL of Exzolt contains 10 mg of fluralaner.

The chemical name of fluralaner is (±)-4-[5-(3,5-dichlorophenyl)-5-(trifluoromethyl)-4,5 dihydroisoxazol-3-yl]-2-methyl-N-[2-oxo-2-(2,2,2-trifluoroethylamino)ethyl] benzamide.

Indications for Use: Exzolt is indicated for the treatment and control of Northern Fowl Mites (*Ornithonyssus sylviarum*) in laying hens and replacement chickens.

Dosage and Administration: Exzolt must be administered orally to chickens via the drinking water as 2 single doses spaced 7 days apart, with each dose consumed over a period of 6 to 24 hours. Each dose is 0.5 mg fluralaner/kg (0.227 mg/lb) body weight, equivalent to 0.05 mL of Exzolt/kg body weight (0.023 mL/lb).

Active Ingredient: fluralaner

General Mixing Directions: Determine the time period over which to administer the medicated water on the treatment day. This period of time must be a minimum of 6 hours and maximum of 24 hours and long enough to allow all birds to receive the required dose. **If the medicated water will contact rusty surfaces, it must be consumed within 8 hours of preparation**. Estimate how much water birds will usually consume during the selected treatment period based on the previous day's water consumption. (This volume is referred to below as "Volume of Medicated Water to be Consumed".) Ensure that the amount of medicated drinking water offered will be consumed completely within the selected treatment period (between 6 and 24 hours). No other source of drinking water should be available during the medication period. Immediately prior to treatment, remove any other source of water so that only medicated water is available to chickens during the treatment period.

Calculate the volume of Exzolt needed based on the total weight of all birds in the house to be treated. To ensure administration of the correct dose, body weight should be estimated as accurately as possible.

The required amount of Exzolt on each treatment day is calculated from the total body weight of the entire group of chickens to be treated:

Volume of Exzolt (mL) per treatment day = Total body weight (kg) of birds to be treated x 0.05 mL/kg Or

Volume of Exzolt (mL) per treatment day = Total body weight (lb) of birds to be treated x 0.023 mL/lb

Examples:

Total body weight of birds to be treated	Volume of Exzolt per treatment day
1 kg (2.2 lb)	0.05 mL
5 kg (11 lb)	0.25 mL
10 kg (22 lb)	0.5 mL
15 kg (33 lb)	0.75 mL
20 kg (44 lb)	1 mL

Use the provided dosing syringe for withdrawing the required volume of Exzolt from the amber glass bottle and mix with the necessary volume of drinking water as described in the following steps.

For each day of treatment, medicated water must be freshly prepared.

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

- Measure the predetermined volume of water to be medicated and consumed into a clean water dispenser, prior to measuring the medication.
- 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 bottle adaptor into the neck of the bottle.
- To dose: Remove the in-use cap. Attach the 1-mL dosing syringe to the bottle by gently pushing the end of the syringe into the bottle adapter.
- 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. The bottle adapter should remain in the neck of the bottle for the duration of use.
- Add the Exzolt in the syringe to a volume of fresh drinking water equivalent to the Volume of Medicated Water to be Consumed and mix. Rinse the 1-mL dosing syringe and add the rinse water to the medicated water. Provide the medicated water to the birds and ensure that all medicated water is consumed within the established treatment time period (i.e. 6 to 24 hours) before re-introducing fresh, non-medicated water.
- Clean and dry the syringe after use. The syringe may be reused for future dose administrations. To ensure long-term control of the mite populations in a treated flock it is essential to treat any other infested poultry in proximity to the treated flock.

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Warnings

WITHDRAWAL PERIODS: Chickens must not be slaughtered for human consumption for 11 days after the last treatment. No egg discard is required when used according to the labeling.

User Safety Warnings: Not for use in humans. Keep this and all drugs out of the reach of children.

Protective gloves should be used. Care should be taken when handling the product to avoid skin and eye exposure, exposure of mucous membranes, and accidental ingestion. Accidental exposure may cause skin and eye irritation. In case of eye contact, immediately rinse thoroughly with water. If wearing contact lenses, immediately rinse the eyes first, then remove contact lenses and continue to rinse the eyes thoroughly. Seek medical advice if symptoms occur. Wash hands and contacted skin with soap and water after use of the product. Remove contaminated clothes and launder with detergent.

Accidental ingestion may cause gastrointestinal disturbances and hypersensitivity reactions in humans.

To obtain a copy of the Safety Data Sheet (SDS) or for technical assistance, call Merck Animal Health at 1-800-211-3573.

Contact Information: Contact Merck Animal Health at 1-800-521-5767 or sp-uspoultrycustomerserviceusa@merck.com. To report suspected adverse drug experiences, contact Livestock Technical Service at 1-800-211-3573. For additional information about reporting adverse drug experiences for animal drugs, contact FDA at 1-888-FDA-VETS or https://www.fda.gov/reportanimalae.

Clinical Pharmacology

Mechanism of Action: Fluralaner is for systemic use and belongs to the class of isoxazoline-substituted benzamide derivatives. Fluralaner acts as an inhibitor of the arthropod nervous system by antagonizing ligand-gated chloride channels (gamma-aminobutyric acid [GABA]-receptor and glutamate-receptor).

Pharmacokinetics: The pharmacokinetics of fluralaner were determined in fifty-five healthy laying hens treated with two single oral administrations of Exzolt (0.5 mg/kg twice) at 7-day intervals via drinking water. Concentrations of fluralaner peaked at 36 hours after the first administration and at 12 hours after the second administration. The maximum concentration (Cmax) of fluralaner was higher after the second dose (355 ng/mL) compared to after the first dose (323 ng/mL) suggesting slight accumulation. In a subsequent study, the oral bioavailability of fluralaner was determined in chickens after intravenous and oral administration (gavage) at a dose of 0.5 mg/kg. The oral bioavailability of fluralaner is 91%.

Target Animal Safety

Two margin of safety studies (growing broiler chickens and laying hens during peak egg production) and two reproductive safety studies (layer and broiler breeder chickens) were conducted.

The margin of safety study in broiler chickens was conducted in 320 3-week-old parent stock broiler chickens (Ross 308) at 1X, 3X, or 5X the recommended dose of 0.5 mg/kg body weight for 3 times the recommended duration at 7-day intervals, and the margin of safety study in laying hens was conducted in 120 commercial laying hens (Novogen) at 1X, 3X, or 5X the label dose for 3 consecutive days each, 7 days apart. No clinically relevant effects related to the administration of Exzolt were observed.

The reproductive safety study in layer chicken breeders was conducted in 432 (48 male and 384 female) commercial Bovans strain layer breeder chickens at 3 times the recommended dose on 4 occasions, 7 days apart and the reproductive safety study in broiler chicken breeders was conducted in 432 (48 male and 384 female) commercial Cobb 500 broiler breeder chickens at 3X the recommended dose on 4 occasions, 7 days apart. No clinically relevant effects on reproductive safety parameters related to the administration of Exzolt were observed.

These studies support the safety of Exzolt in laying hens and replacement chickens when administered in drinking water as 2 single doses of 0.5 mg/kg body weight, 7 days apart.

Effectiveness

In a well-controlled dose confirmation study conducted in 128 commercial 14-week-old White Leghorn female replacement chickens (Hy-Line® strain), effectiveness against *Ornithonyssus sylviarum* was 100% on Days 8, 14, 19, and 28 after the first treatment. No treatment-related adverse events were observed.

In a well-controlled dose confirmation study conducted in 128 commercial 29-week-old Brown Leghorn laying hens (Hy-Line strain), effectiveness against *Ornithonyssus sylviarum* was 100% on Days 8 and 14 after the first treatment. No treatment-related adverse events were observed.

In a well-controlled field effectiveness study conducted in 800 commercial 23-week-old White Leghorn laying hens (Hy-Line strain), effectiveness against *Ornithonyssus sylviarum* exceeded 99.9% on Days 8, 14, 19, and 28 after the first treatment. No treatment-related adverse events were observed.

In a well-controlled field effectiveness study conducted in 800 commercial 28-week-old White Leghorn (Hy-Line strain) laying hens, effectiveness against *Ornithonyssus sylviarum* exceeded 99.9% on Days 8, 14, 19, and 28 after the first treatment. No treatment-related adverse events were observed.

In all 4 effectiveness studies Exzolt achieved 99.3% or greater reduction in *Ornithonyssus sylviarum* mite counts on Day 2 following the first dose administration.

How Supplied: Exzolt is available in a 4-mL amber glass container.

Storage and Handling: Store Exzolt at or below 86°F (30°C) and use within 12 months after first opening. Use the medicated water within 24 hours of preparation. **Use within 8 hours of preparation if the medicated water comes in contact with rusty surfaces**.

Approved by FDA under NADA # 141-607

Formulated in France.

Distributed By: Intervet Inc. (d/b/a Merck Animal Health), 126 E. Lincoln Avenue, Rahway, NJ 07065

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