PRODUCT BULLETIN

EXZOLT™

(fluralaner oral solution)

10mg of fluralaner/mL

Exzolt is indicated for the treatment and control of northern fowl mites (*Ornithonyssus sylviarum*) in laying hens and replacement chickens.

ADVANTAGES*:

- Rapid and massive decrease in mite populations in a chicken house, with demonstrated 99%+ efficacy*
- Full treatment by convenient application via drinking water 2 times, 7 days apart
- Ready-to-use solution for simple dilution, with no sedimentation, clogging or spoilage
- Zero-day egg withdrawal period, ideal for commercial layers
- 11-day meat withdrawal after last administration of Exzolt
- More effective, safe, targeted and convenient than mite sprays
- Fast onset of acaricidal activity, with 99%+ reduction in northern fowl mite counts after just 2 days. Full treatment requires 2 administrations, 7days apart, which spans two mite life cycles, disrupting mite population dynamics

Exzolt™ is a fluranlaner oral solution for control of Northern Fowl mites available in 1L and 4L presentations.

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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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).

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. 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.

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 and an accurate device should be used for measuring the calculated volume of product to be administered.

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
5000 kg (11,023 lb)	0.25 L (250 mL)
10,000 kg (22,046 lb)	0.5 L (500 mL)
15,000 kg (33,069 lb)	0.75 L (750 mL)
20,000 kg (44,092 lb)	1 L (1,000 mL)
80,000 kg (176,370 lb)	4 L
320,000 kg (705,479 lb)	16 L

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

- 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 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).
- Prior to introducing the medicated water, drain the drinker lines fully by opening the flush valve and checking end-line nipples to ensure no water remains.
- Prime the drinker lines with medicated water and confirm the medicated water has reached all end-line nipples.

Once the stock solution container is empty, rinse both the container and downstream water lines with unmedicated water (rinse water). Allow birds to consume the rinse water before reintroducing non-medicated water. The full course of therapy (2 single doses 7 days apart) must be administered for full therapeutic effect. Strict biosecurity measures at house and farm level should be implemented to prevent reinfestation 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.

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 1- and 4-liter HDPE plastic containers.

Storage and Handling: Store Exzolt at or below 86°F (30°C) and use within 6 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

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

Revision Date 05/2025

230477 R10

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