

Product Name: EXZOLT FLURALANER ORAL SOLUTION FOR CHICKENS
 APVMA Approval No: 85688/134447



Label Name:	EXZOLT FLURALANER ORAL SOLUTION FOR CHICKENS
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Signal Headings:	<p>CAUTION</p> <p>KEEP OUT OF REACH OF CHILDREN</p> <p>FOR ANIMAL TREATMENT ONLY</p> <p>READ SAFETY DIRECTIONS</p>
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Constituent Statements:	10 g/L FLURALANER
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Claims:	<p>Treatment and control of poultry red mite (<i>Dermanyssus gallinae</i>) infestation in pullets, breeders and layer hens.</p> <p>EFFICACY AND ONSET OF ACTION</p> <p>Fluralaner is an acaricide and insecticide that has a high potency against poultry red mite, mostly by exposure via feeding, i.e. it is systemically active against the target parasites.</p> <p>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.</p> <p>The onset of efficacy against <i>Dermanyssus gallinae</i> is within 4 hours of mites starting to feed on treated chickens.</p> <p>The treatment kills mites feeding on treated chickens for 15 days after the first administration of the product. Female mites are killed before viable eggs are produced and this breaks the mite life cycle.</p> <p>In vitro bio-assays show that fluralaner is effective against <i>Dermanyssus gallinae</i> strains that have shown field resistance to phoxim (organophosphate), deltamethrin (pyrethroid) and propoxur (carbamate).</p> <p>As demonstrated in a multi-site 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).</p> <p>Resistance may develop to any parasiticide.</p>
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Net Contents:	50 mL, 1 L, 2.5 L, 4 L, 5 L, 10 L, 15 L, 20 L, 25 L
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Directions for Use:	
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Restraints:	
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Contraindications:	
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Precautions:	Do not use on chickens less than 3 weeks of age.
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Side Effects:	
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Dosage and Administration:	<p>Once diluted use the medicated water within 24 hours of mixing.</p> <p>Use the contents within 1 year of first opening the container. Discard the unused portion. Do not use rusty metal containers for diluted product.</p> <p>For use in drinking water.</p> <p>A complete course of treatment consists of two doses, administered 7 days apart. One dose is 0.5 mg fluralaner per kg body weight (equivalent to 0.05 mL of product). The complete course of treatment must be administered for a full therapeutic effect.</p> <p>If another course of treatment is indicated, the interval between two courses of treatment should be at least 3 months.</p> <p>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.</p> <p>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.</p> <p>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:</p> <p>Volume of product (mL) per treatment day = Total body weight (kg) of chickens to be treated x 0.05 mL/kg.</p> <p>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.</p> <p>The instructions below need to be followed, in the order described, to prepare the medicated water:</p> <ul style="list-style-type: none"> - 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.
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	<ul style="list-style-type: none"> - 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. <p>After each treatment administration, fill the stock solution container with clean (unmedicated) water to rinse the water lines.</p>
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General Directions:	<p>NOT TO BE USED FOR ANY PURPOSE, OR IN ANY MANNER, CONTRARY TO THIS LABEL UNLESS AUTHORISED UNDER APPROPRIATE LEGISLATION.</p> <p>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.</p> <p>The safety of the veterinary medicinal product has been demonstrated in layers and breeders. The product can be used during lay.</p> <p>The following practices should be avoided because they increase the risk of development of resistance and could ultimately result in ineffective therapy:</p> <ul style="list-style-type: none"> - 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. <p>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.</p> <p>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.</p> <p>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.</p> <p>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 eggs, and fluralaner is mainly eliminated via the hepatic route. The apparent elimination half-life is approximately 5 days following oral administration.</p>
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	<p>Fluralaner is part of the isoxazoline family of chemicals. Adverse reactions to this family of chemicals are rarely observed but may include diarrhoea, lethargy, inappetance, itching and very rarely, seizures. Most adverse reactions are self-limiting and of short duration. If you have any concerns, please speak to your veterinarian.</p>
Withholding Periods:	<p>MEAT: DO NOT USE less than 14 days before slaughter for human consumption. EGGS: Zero (0) days.</p>
Trade Advice:	
Safety Directions:	<p>May irritate the eyes and skin. Avoid contact with eyes and skin. When opening the container and preparing the product for use wear disposable gloves. Wash hands after use.</p>
First Aid Instructions:	<p>If poisoning occurs, contact a doctor or Poisons Information Centre. Phone Australia 131126. If skin contact occurs, remove contaminated clothing and wash skin thoroughly.</p>
First Aid Warnings:	
Additional User Safety:	<p>Additional information is listed in the safety data sheet.</p>
Environmental Statements:	<p>ENVIRONMENTAL PROTECTION Do not contaminate dams, rivers, streams or other waterways with the chemical or used container.</p>
Disposal:	<p>[For 50 mL, 1 L pack sizes] Dispose of container by wrapping in paper and putting in garbage.</p> <p>[For 2.5 L, 4 L, 5 L, 10 L, 15 L, 20 L, 25 L pack sizes] Triple-rinse container and dispose of rinsate in compliance with relevant local, state or territory government regulations. Do not dispose of undiluted chemicals on-site. If the container has the drumMUSTER logo visible, and has been thoroughly cleaned and dried, and is free of any visible residues, it can be recycled at any drumMUSTER collection or similar container management program site. The cap should not be replaced, but may be recycled separately at the drumMUSTER collection site. If not recycling, break, crush, or puncture container and deliver to an approved waste management facility. If an approved waste management facility is not available, bury the broken, crushed or punctured containers 500 mm below the surface in a disposal pit specifically marked and set up for this purpose clear of waterways, vegetation and tree roots, in compliance with relevant local, state or territory government regulations. Do not burn empty containers or product.</p>
Storage:	<p>Store below 30°C (room temperature) in the tightly closed, original container in a cool dry place. Do not store for prolonged periods in direct sunlight.</p>