

## **For Animal Use Only**

### **DELTANIL**

Pour-on Solution

Veterinary Insecticide-Acaricide

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#### **Composition**

Deltanil Pour-on Solution is a clear, slightly yellow oily solution containing 10 mg of deltamethrin per ml.

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#### **Pharmacological Properties**

##### **Pharmacodynamics**

Deltamethrin is a synthetic pyrethroid with insecticidal and acaricidal effects. It is one of a wide range of pyrethroid esters developed as synthetic analogs of the original insecticidal extracts isolated from pyrethrum flowers. Deltamethrin is an alpha-cyano pyrethroid and a member of the second-generation pyrethroids. In second-generation pyrethroids, the overall stability of the molecule has been improved, with increased resistance to photo- and bio-degradation and enhanced insecticidal effects. It exhibits stronger toxicity to insects and acari due to its slower metabolic rate.

The exact mechanism of insecticidal action of pyrethroids is not fully understood, but they have strong neurotoxic effects in insects, resulting in sensory coordination disturbances, irregular motor activity, and destructive effects. Pyrethroids are metabolized much faster in mammals through oxidative and neurotoxic pathways, so neurotoxic effects are seen at much higher doses than those needed for ectoparasitic effects.

Resistance to deltamethrin may result from two physiological mechanisms: mutation of the molecular target of deltamethrin or through metabolic enzymes like glutathione-S-transferase.

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##### **Pharmacokinetics**

After topical application, deltamethrin is slowly absorbed through the skin of cattle and sheep. Pyrethroids are metabolized via oxidative and neurotoxic pathways. The primary route of excretion for absorbed amounts in target animals is through feces.

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##### **Environmental Impact**

Deltamethrin has the potential to negatively affect non-target organisms. After treatment, deltamethrin is excreted in feces, and its elimination may take 2 to 4 weeks. Excretion of deltamethrin in feces from treated animals can reduce the number of

organisms in manure-fed systems.

Deltamethrin is highly toxic to manure fauna, aquatic organisms, and honeybees, is persistent in soil, and can accumulate in sediments.

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### Indications for Use

For regional application, it is used in cattle for the treatment and prevention of infestations caused by lice and flies, in sheep for the treatment and prevention of ticks, lice, sheep louse, and blowflies, and in lambs for lice and tick infestations.

**In Cattle:** For the treatment and prevention of infestations caused by both biting and bloodsucking lice including *Bovicola bovis*, *Solenopotes capillatus*, *Linognathus vituli*, and *Haematopinus eurysternus*. Also used for the treatment and prevention of infestations caused by biting and nuisance flies such as *Haematobia irritans*, *Stomoxys calcitrans*, *Musca* species, and *Hydrotaea irritans*.

**In Sheep:** For the treatment and prevention of infestations by ticks (*Ixodes ricinus*), lice (*Linognathus ovillus*, *Bovicola ovis*), sheep louse (*Melophagus ovinus*), and blowflies (*Lucilla* spp.).

**In Lambs:** For the treatment and prevention of infestations by ticks (*Ixodes ricinus*) and lice (*Bovicola ovis*).

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### Dosage and Application Method

For external use only. Apply as a pour-on solution to the skin.

**Cattle:** 100 mg of deltamethrin per animal, which is 10 ml of product.

**Sheep:** 50 mg of deltamethrin per animal, which is 5 ml of product.

**Lambs (under 10 kg body weight or less than 1 month old):** 25 mg of deltamethrin per animal, which is 2.5 ml of product.

### Application:

The product should be applied using an appropriate applicator.

- For 0.5 L and 1 L bottles, the product is supplied with a dosing cup.
- For 2.5 L bottles and flexible bags (2.5 L and 4.5 L), it is recommended to use an appropriate dosing gun. Flexible bags should be carried in a suitable backpack. The applicator should meet the following criteria:
  - Capable of dosing 2.5 mL, 5 mL, and 10 mL doses.
  - Should be supplied with a flexible hose with inner diameters of 10 mm and 14 mm.

**For Cattle:** Apply a 10 ml dose using a suitable applicator.

**For Sheep:** Apply a 5 ml dose using a suitable applicator.

**For Lambs:** Apply a 2.5 ml dose using a suitable applicator.

**Application Area:**

Apply along the midline of the back at shoulder height. Follow the special instructions below:

**Lice Infestation in Cattle:** One application will typically eradicate all lice. It may take 4–5 weeks for complete elimination, during which eggs hatch and lice die. A few lice may remain alive on a few animals.

**Fly Infestation in Cattle:** In areas with a high number of horn flies, treatment and prevention may take 4-8 weeks.

**Tick Infestation in Sheep:** A treatment along the midline of the shoulders will treat and prevent tick infestations for up to 6 weeks after treatment in animals of all ages.

**Lice Infestation in Sheep:** A treatment along the midline of the shoulders will reduce the incidence of biting lice and sheep lice for 4-6 weeks post-treatment in short or long wool sheep.

It is advised to treat sheep shortly after wool shearing (for short wool sheep) and separate treated animals from untreated ones.

**Blowfly Infestation in Sheep:** Apply directly to the infected area if blowfly infestation is seen. A single application will cause blowfly larvae to die shortly after. In more severe infestations, it is recommended to trim dirty wool before application.

**Tick and Lice Infestation in Lambs:** Treatment along the midline of the back at shoulder height will provide treatment and protection against tick infestations for up to 6 weeks and will reduce the incidence of biting lice for 4-6 weeks after treatment.

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**Special Clinical Information and Warnings**

Deltamethrin is an irritant; do not apply it to the eyes or mucous membranes of animals. The product is for external use only. Care should be taken to prevent animals from licking the product. Avoid using the product in very hot weather and ensure animals have adequate access to water. The product should only be applied to undamaged skin, as toxicity may occur due to absorption through large skin lesions. However, localized irritation may occur following treatment, as the skin is already affected by infestations. To prevent resistance, the product should only be used if the local fly population is confirmed to be sensitive to the active ingredient. If clinical signs do not improve after treatment, the diagnosis should be re-evaluated. Resistance to deltamethrin in biting and nuisance flies and lice has been reported in cattle and sheep. Where resistance to deltamethrin is known, the product should be used based on the results of a sensitivity test. For more information, consult your veterinarian. The product will reduce the number of flies directly on the animal, but it is not expected to eliminate all flies on the

farm. Therefore, its strategic use should be based on local and regional epidemiological information about parasite sensitivity and should be used in conjunction with other parasitic control methods.

To reduce the risk of resistance development, and to avoid ineffective treatment, the following practices should be avoided:

- Frequent and prolonged use of other ectoparasitic drugs from the same class.
- Incorrect dosage due to inaccurate estimation of body weight, faulty application of the product, or miscalibrated dosing devices.

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### **Use During Pregnancy and Lactation**

The safety of Deltanil during pregnancy and lactation has not been studied. No teratogenic effects were observed in laboratory studies on rats and rabbits. During pregnancy or lactation, it should only be used according to a benefit/risk assessment by a responsible veterinarian.

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### **Undesirable Effects**

In very rare cases, after treatment, reactions such as scaling and itching at the application site may be observed in cattle for up to 48 hours.

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### **Drug Interactions**

Do not use in combination with other insecticides or acaricides, especially organophosphate compounds, as deltamethrin toxicity is increased when used with these substances.

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### **Overdose Symptoms, Precautions, and Antidote**

Some adverse effects have been observed following overdose, including paresthesia and irritation in cattle, and intermittent urination in young lambs. These effects were mild, temporary, and resolved spontaneously without treatment.

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### **Contraindications**

Do not use in animals that are recovering or ill. Do not use in animals that are hypersensitive to the active or excipient ingredients.

Do not use in animals with severe skin lesions.

Non-target species, such as dogs and cats, may suffer toxic neurological signs (ataxia,

convulsions, tremors) and gastrointestinal symptoms (hypersalivation, vomiting) if used outside of the labeled species and may be fatal.

### **Residue Warnings for Food-Producing Animals**

Drug Withdrawal Time (DWT):

- For cattle, animals should not be sent for slaughter before 17 days after the last treatment.
  - For sheep, animals should not be sent for slaughter before 35 days after the last treatment.
  - The withdrawal period for milk in cattle and sheep is "0" days.
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### **General Warnings**

- Always read the prospectus before use. If any unexpected effects occur, consult your veterinarian.
  - Store the product in its original packaging, away from food, drinks, and animal feed, in a secure location out of children's reach.
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### **Precautions for Users and Recommendations for Veterinarians**

- Persons known to be hypersensitive to the product or its components should avoid contact with the veterinary medicinal product.
- Wear waterproof gloves, boots, and protective clothing while applying the product or handling animals that have been treated.
- Immediately remove heavily contaminated clothing and wash it before reusing.
- Wash skin areas exposed to the product immediately with soap and plenty of water.
- After handling the product, wash hands and any exposed skin areas before eating, drinking, or smoking.
- In case of eye contact, rinse immediately with plenty of clean, running water and seek medical attention.
- If accidentally swallowed, rinse mouth with plenty of water, seek medical help immediately, and show the product label to the doctor.
- Do not eat, drink, or smoke while handling this product.

This product may cause tingling, itching, and red spots on the skin of people exposed to it. If you feel unwell after working with the product, seek medical attention and show the product's prospectus or label to the doctor.

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### **Disposal of Unused Product and Non-target Species Warnings**

Unused or leftover product should be disposed of in accordance with local regulations. Deltamethrin is highly toxic to manure fauna, aquatic organisms, and honeybees. It is persistent in soil and can accumulate in sediments. To minimize environmental risk, the use of deltamethrin (and other synthetic pyrethroids) in cattle and sheep should be limited by avoiding frequent and repeated applications in the same pasture (e.g., only one treatment per year per pasture).

To further reduce the risk to aquatic ecosystems, prevent treated sheep from entering water sources for at least one hour after treatment.

The product should not be disposed of in waste water, water sources, or drainage systems. Deltamethrin is persistent in soil and has been shown to accumulate.

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### **Storage Conditions and Shelf Life**

Store in the tightly closed original packaging, away from food, drink, and animal feed.

The shelf life of the product in its saleable packaging is 5 years from the production date.

For bottles, once opened, the shelf life is 1 year.

For flexible bags, once opened, the shelf life is 2 years.

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### **Commercial Presentation**

The product is available in the following forms:

- 500 ml and 1-liter white high-density polyethylene bottles with a removable aluminum seal, a PP dosing device with compartments for dosing 2.5 ml, 5 ml, and 10 ml, and a HDPE cap.
  - 2.5-liter white high-density polyethylene bottles with a PP cap and ventilation cap with a PP coupling.
  - 2.5-liter and 4.5-liter multi-layer PET/aluminum/PA/PE flexible bags with an "E-lock" POM coupling.
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### **Sales Location and Conditions**

Sold with a veterinary prescription at pharmacies, veterinary clinics, polyclinics, and animal hospitals (VHR).

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**Marketing Authorization Holder and Address:**

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