

## **SUMMARY OF PRODUCT CHARACTERISTICS**

### **1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Deltanil 100 mg Spot-on Solution for cattle

### **2. QUALITATIVE AND QUANTITATIVE COMPOSITION**

Each 10 ml tube contains

**Active substance:**

Deltamethrin 100 mg

For a full list of excipients, see section 6.1.

### **3. PHARMACEUTICAL FORM**

Spot-on Solution  
Slightly yellowish clear oily solution.

### **4. CLINICAL PARTICULARS**

#### **4.1 Target species**

Cattle

#### **4.2 Indications for use, specifying the target species**

As a topical application for the treatment and prevention of infestations by lice and flies on cattle.

For the treatment and prevention of infestations by both sucking and biting lice, including *Bovicola bovis*, *Solenopotes capillatus*, *Linognathus vituli* and *Haematopinus eurysternus*. Also as an aid in the treatment and prevention of infestations by both biting and nuisance flies including *Haematobia irritans*, *Stomoxys calcitrans*, *Musca* species and *Hydrotaea irritans*.

#### **4.3 Contraindications**

Do not use on convalescent or sick animals.

Do not use in cases of known hypersensitivity to the active substance or any of the excipients.

Extra-label use of the product in the non-target species dogs and cats can lead to toxic neurological signs (ataxia, convulsions, tremors), digestive signs (hypersalivation, vomiting) and may be fatal.

#### **4.4 Special warnings <for each target species>**

Do not apply on or near the animal's eyes and mucous membranes.

To avoid resistance, the product should only be used if the susceptibility of the local fly population to the active substance is assured. If clinical signs do not resolve following treatment, the diagnosis should be revised.

Cases of resistance to deltamethrin have been reported in stinging and nuisance flies in cattle.

In countries with recognized resistance to deltamethrin the use of the product should ideally be based on results of susceptibility testing. Please, ask your veterinarian for further information.

The product will reduce the number of flies resting directly on the animal but it is not expected to eliminate all flies on a farm. The strategic use of the product should, therefore, be based on local and regional epidemiological information about susceptibility of parasites, and used in association with other pest management methods.

Care should be taken to avoid the following practices because they increase the risk of development of resistance and could ultimately result in ineffective therapy:

- too frequent and repeated use of ectoparasiticides from the same class over an extended period of time;
- underdosing which may be due to underestimation of bodyweight, misadministration of the product.

#### **4.5 Special precautions for use**

(i) Special precautions for use in animals

The product is for external use only.

Avoid contact with eyes and mucous membranes as Deltamethrin is an irritant.

Care should be taken to prevent licking of the product. Avoid use of the product during extremely hot weather and ensure animals have adequate access to water.

The product should only be administered onto undamaged skin as toxicity is possible due to absorption from major skin lesions. However, signs of local irritation may occur after treatment as skin may be already affected by infestation.

(ii) Special precautions to be taken by the person administering the veterinary medicinal product to animals

Persons with known hypersensitivity to the product or one of its components should avoid contact with the veterinary medicinal product.

Wear protective clothing including waterproof apron and boots and impervious gloves when either applying the product or handling recently treated animals.

Remove heavily contaminated clothing immediately and wash before re-use.

Wash splashes from skin immediately with soap and plenty of water.

Wash hands and exposed skin after handling this product and before meals.

In case of contact with eyes, rinse immediately with plenty of clean, running water and seek medical advice.

In case of accidental ingestion, wash out mouth immediately with plenty of water, seek medical advice and show the package leaflet to the physician.

Do not smoke, drink or eat while handling the product.

This product contains deltamethrin which may produce tingling, itchiness and blotchy redness on exposed skin. If you feel unwell after working with this product, consult your doctor and show this label.

### **Other precautions**

Deltamethrin is toxic to dung insects. The risk to dung fauna can be reduced by avoiding too frequent and repeated use of deltamethrin (and other synthetic pyrethroids) in cattle, e.g. by using a single treatment per year on the same pasture.

#### **4.6 Adverse reactions (frequency and seriousness)**

Squamosis and pruritus have been seen in some cattle during the 48 hours after treatment.

#### **4.7 Use during pregnancy, lactation or lay**

Laboratories studies (rat, rabbits) have not produced any evidence of teratogenic or embryotoxic effects.

No studies have been conducted with the product in pregnant cows and ewes.

The product can be used in cows during pregnancy and lactation only accordingly to the benefit/risk assessment by the responsible veterinarian.

#### **4.8 Interaction with other medicinal products and other forms of interaction**

Do not use with any other insecticide or acaricide. Especially, in combination with organo-phosphorous compounds, the toxicity of deltamethrin is enhanced.

#### **4.9 Amounts to be administered and administration route**

For external use.

**Dose:** 100 mg of deltamethrin per cattle corresponding to the entire content of the 10 ml tube.

#### **Administration:**

Apply the entire contents of the 10 ml tube

Application site :

Apply the product on one spot on the mid-line of the back at the shoulders.

Lice: One application will generally eradicate all lice. Complete clearance of all lice may take 4 - 5 weeks during which time lice hatch from the eggs and are killed. A very few lice may survive on a small minority of animals.

Flies: Where horn-flies predominate, treatment and prevention of infestations can be expected for 4 - 8 weeks.

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

Some adverse effects have been seen following overdose. These include paraesthesia and irritation and have been shown to be mild, transient and resolve without treatment.

#### **4.11 Withdrawal periods**

Meat and offal: 17 days

Milk: zero hours

### **5. PHARMACOLOGICAL PROPERTIES**

**Pharmacotherapeutic group**: Ectoparasiticide for topical use, including insecticides. Pyrethrins and pyrethroids.

**ATCvet code**: QP53AC11

#### **5.1 Pharmacodynamic properties**

Deltamethrin is a synthetic pyrethroid possessing insecticidal and acaricidal activity. It is one of a large family of pyrethroid esters which have evolved as synthetic analogues of the original insecticidal extracts isolated from powdered pyrethrum flowers. Deltamethrin is an alpha- cyano pyrethroid and is a member of the second generation of pyrethroids in which the overall stability of the molecule is improved with correspondingly increased resistance to photo- and bio-degradation and enhanced insecticidal activity. It is more potently toxic to insects and acarines because of the slower rate of metabolism.

The precise mode of insecticidal activity of pyrethroids remains uncertain, but they are potent neurotoxins in insects, causing failure in sensory coordination and disorganised motor activity, hence the 'knock-down' effect. Pyrethroids are metabolised through oxidative and neurotoxic pathways far more rapidly in mammals, so that neurotoxic effects can only occur at dosages which are many orders of magnitude greater than those required for ectoparasitic activity.

Two physiological mechanisms are likely to contribute to deltamethrin-resistance: mutation of the molecular deltamethrin target or through metabolic enzyme glutathione-S-transferases.

## **5.2 Pharmacokinetic particulars**

After dermal application, deltamethrin is slightly absorbed through skin of cattle. Pyrethroids are metabolised through oxidative and neurotoxic pathways. The main route of excretion of the absorbed amount in the target animal is the faeces.

### **Environmental properties**

Deltamethrin has the potential to adversely affect non-target organisms. Following treatment, deltamethrin is excreted in faeces. Deltamethrin excretion may take place over a period of 2 to 4 weeks. Faeces containing deltamethrin excreted onto pasture by treated animals may reduce the abundance of dung feeding organisms.

Deltamethrin is toxic to aquatic organisms and honey bees and may accumulate in sediment.

## **6. PHARMACEUTICAL PARTICULARS**

### **6.1 List of excipients**

Triglycerides medium-chain

### **6.2 Incompatibilities**

None known.

### **6.3 Shelf life**

Shelf-life of the veterinary medicinal product as packaged for sale: 3 years

### **6.4. Special precautions for storage**

Store in tightly closed original container away from food, drink and animal feeding stuffs.

### **6.5 Nature and composition of immediate packaging**

10 ml white high-density polyethylene tube placed in a carton box.  
Carton box of 10 tubes.

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

Dangerous to fish and other aquatic life. Do not contaminate ponds, waterways or ditches with the product or used container.

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

**7. MARKETING AUTHORISATION HOLDER**

VIRBAC  
1ère avenue – 2065m – L.I.D.  
06516 Carros  
FRANCE

**8. MARKETING AUTHORISATION NUMBER**


**Vm** 05653/4169

**9. DATE OF FIRST AUTHORISATION**

**Date:** 20 March 2014

**10. DATE OF REVISION OF THE TEXT**

**Date:** November 2014

**APPROVED**  **14/11/14**