

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Fly and Lice Spot On Insecticide 10 mg/ml spot-on solution for cattle and sheep

## 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

### Active substance:

Deltamethrin (Technical) 10 mg

### Excipient:

Qualitative composition of excipients and other constituents
Coconut Oil Fractionated

A clear, pale gold, oily solution.

## 3. CLINICAL INFORMATION

### 3.1 Target species

Cattle and sheep.

### 3.2 Indications for use for each target species

As a topical application for the control of lice and flies on cattle and ticks, lice, keds and established blowfly strike on sheep.

On cattle: for the control of both sucking and biting lice, including *Damalinia bovis*, *Solenopotes capillatus*, *Linognathus vituli* and *Haematopinus eurysternus* on all ages of cattle including dairy cattle producing milk for human consumption. Also as an aid in the control of both biting and nuisance flies including *Haematobia irritans*, *Stomoxys calcitrans*, *Musca* species and *Hydrotaea irritans*.

On sheep: For the control of ticks (*Ixodes ricinus*) and of lice and keds and established blowfly strike.

### 3.3 Contraindications

Do not use in ewes producing milk for human consumption.

Do not use in cases of hypersensitivity to the active substance.

### 3.4 Special warnings

For external use only.

### 3.5 Special precautions for use

#### Special precautions for safe use in the target species:

The product has been applied safely at the recommended rate to day old animals and to calves less than 14 days of age.

#### Special precautions to be taken by the person administering the veterinary medicinal product to animals:

In case of accidental ingestion wash out mouth immediately and seek medical advice immediately and show the package leaflet or the label to the physician.

A transient tingling sensation on the skin may occur if deltamethrin comes in contact with the face of some individuals. It is therefore advisable that the following precautions should be observed:

Personal protective equipment consisting of protective gloves should be worn when handling the veterinary medicinal product and when handling recently treated animals.

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

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

Wash hands and exposed skin before meals or smoking and after work.

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

#### Special precautions for the protection of the environment:

Not applicable.

### 3.6 Adverse events

Cattle and sheep:

Very rare ( $<1$ animal / 10,000 animals treated, including isolated reports):	Lacrimation <sup>1</sup> Discomfort <sup>2</sup>
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<sup>1</sup> Observed in cattle only.

<sup>2</sup> Minor; may occur for up to 48 hours after treatment. This action is short term and is not detrimental to the animal.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

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

#### Pregnancy and lactation:

Can be used during pregnancy and lactation.

No special precautions are recommended.

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

Do not mix any other insecticide or acaricide with the product.

### **3.9 Administration routes and dosage**

Dose:

Cattle: 10 ml.

Sheep: 5 ml.

Established blowfly strike -5 ml.

Administration: Apply a single dose with the special 'Squeeze 'n' Pour' dispenser pack or the applicator on one spot on the mid-line of the back at the shoulders as directed on the dispenser or applicator gun pack. For blowfly strike on sheep, see following specific indication directions:

***Lice on cattle:*** 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. Therefore, it may be necessary on rare occasions to re-treat an animal 6 - 8 weeks later.

***Flies on cattle:*** To control biting and non-biting flies, treatment should be repeated as necessary. Frequency of treatment will depend on the numbers and species of flies present. Where horn-flies predominate, good control can be expected for 4 - 8 weeks. Re-treat as necessary.

***Ticks on sheep:*** Application to the mid-point of the shoulders will provide useful control of ticks attaching to animals of all ages, for a 4 - 6 week period after treatment.

***Keds and lice on sheep:*** Application to the mid-point of the shoulders of sheep in short or long fleece will reduce the incidence of a biting louse or ked infestation over a 4 - 6 week period after treatment.

N.B. For control of ticks, keds and lice on sheep, the fleece should be parted and the product applied to the skin of the animal.

***Established blowfly strike on sheep:***

Apply directly to the maggot infected area as soon as the fly strike is seen. One application will ensure blowfly larvae are killed in a short time. In the case of more advanced strike lesions, clipping out of stained wool before treatment is advisable.

**3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)**

The product has been shown to be safe in all species even when given at up to five times the recommended therapeutic dose. Some adverse symptoms have been seen in animals treated at overdose, paraesthesia and irritation in cattle and intermittent or attempted urination in young lambs, but these have been shown to be mild, transient and resolve without treatment.

**3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance.**

Not applicable.

**3.12 Withdrawal periods**

Cattle:

Meat and offal: 17 days.

Milk: Zero hours.

Sheep:

Meat and offal: 35 days.

Milk: Not authorised for use in animals producing milk for human consumption.

**4. PHARMACOLOGICAL INFORMATION**

**4.1 ATCvet code: QP53AC11**

**4.2 Pharmacodynamics**

Deltamethrin is a synthetic pyrethroid possessing pesticidal 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 co-ordination 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 pesticidal activity.

## **5. PHARMACEUTICAL PARTICULARS**

### **5.1 Major incompatibilities**

None known.

### **5.2 Shelf life**

Shelf life of the veterinary medicinal product as packaged for sale (200 ml, 500 ml and 1 litre presentations): 5 years.

Shelf life of the veterinary medicinal product as packaged for sale (2.5 litre and 5 litre (2 x 2.5 litre) presentations): 3 years.

### **5.3 Special precautions for storage**

Do not store above 25 °C.

Protect from frost.

Keep the bottle tightly closed.

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

1 litre and 2.5 litre plastic flexi pack for use with an applicator.

A 5 litre pack is also available, containing 2 x 2.5 litre plastic flexi packs for use with an applicator. 250 and 500 ml squeeze and pour dispensers.

Not all pack sizes may be marketed.

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

Medicines should not be disposed of via wastewater or household waste.

The veterinary medicinal product should not enter water courses as Deltamethrin (Technical) may be dangerous for fish and other aquatic organisms.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

**6. NAME OF THE MARKETING AUTHORISATION HOLDER**

Zoetis Belgium S.A.

**7. MARKETING AUTHORISATION NUMBER(S)**

VPA10387/048/001

**8. DATE OF FIRST AUTHORISATION**

04 July 2014

**9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS**

30 September 2024

**10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS**

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the [Union Product Database](https://medicines.health.europa.eu/veterinary) (<https://medicines.health.europa.eu/veterinary>).