Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Fly and Lice Spot On Insecticide 1% w/v

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Substance
Deltamethrin (Technical) 1.00 % w/v

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Spot-on solution.

4 CLINICAL PARTICULARS

4.1 Target Species

Cattle and sheep.

4.2 Indications for use, specifying the 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.

4.3 Contraindications

Do not use the product in ewes producing milk for human consumption.
Do not use the product in animals with known hypersensitivity to the active ingredient.

4.4 Special warnings for each target species

No special warnings are considered necessary.

4.5 Special precautions for use

Special precautions for use in animals
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
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:
Wear protective gloves when applying the product or 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.
In case of accidental ingestion, wash out mouth immediately with water and seek medical advice.

4.6 Adverse reactions (frequency and seriousness)

Minor signs of discomfort have been seen in some cattle during the 48 hours after treatment. This is of no long-term detriment to the animal.
Lacrymation may also be seen in some cattle after treatment.

4.7 Use during pregnancy, lactation or lay

No special precautions are recommended. This product may be used in pregnant and lactating animals.

4.8 Interaction with other medicinal products and other forms of interactions

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

4.9 Amounts to be administered and administration route

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.

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

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.

4.11 Withdrawal period(s)

Cattle:
Meat and offal: 17 days
Milk: Zero hours

Sheep:
Meat and offal: 35 days
Milk: Not for use in ewes producing milk for human consumption.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Phamacotherapeutic group: Ectoparasiticides for topical use, including insecticides, deltamethrin.
ATCvet code: QP53AC11

5.1 Pharmacodynamic properties

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 pyrethoids 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.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Coconut Oil Fractionated

6.2 Major incompatibilities

None known.

6.3 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

6.4 Special precautions for storage

Keep container tightly closed. Do not store above 25°C. Protect from frost.

6.5 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.

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

Dangerous to fish and other aquatic animals.
Do not contaminate ponds, waterways or ditches with the product or used container.
Unused product or waste material should be disposed of in accordance with current practice for pharmaceutical waste under national waste disposal regulations.

7 MARKETING AUTHORISATION HOLDER

Zoetis Belgium S.A.

2nd Floor, Building 10
Cherrywood Business Park, Loughlinstown
Co Dublin
Ireland

8 MARKETING AUTHORISATION NUMBER(S)

VPA10387/048/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 01 October 1999
Date of last renewal: 30 September 2009

10 DATE OF REVISION OF THE TEXT

June 2019