

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF VETERINARY MEDICINAL PRODUCT

Fly & Lice Spot On Insecticide 1 % w/v Cutaneous Solution

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

| Active Substances | % w/v |
|-------------------|-------|
|-------------------|-------|

| | |
|--------------|------|
| Deltamethrin | 1.00 |
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For a full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Cutaneous Solution.
A clear pale gold oily liquid.

4. CLINICAL PARTICULARS

4.1 Target Species

Cattle and sheep.

4.2 Indications for Use

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

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.

On lambs: For the control of ticks *Ixodes ricinus* and lice *Bovicola ovis*.

4.3 Contra-indications and warnings

None

4.4 Special warning for each target species

No special warnings are considered necessary.

4.5 Special precautions for use

- (i) Special precautions for use in animals

For external use only.

- (ii) Special precautions to be taken by the person administering the product to the animal

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 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 and seek medical advice.

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.

Advice to medical practitioners: Advice on clinical management is available from the National Poisons Information Service.

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.

4.7 Use during pregnancy and lactation

No special precautions are recommended.

4.8 Interaction with other medicaments and other forms of interaction:

Do not mix any other insecticide or acaricide with Fly & Lice Spot On Insecticide.

4.9 Amounts to be administered and administration route

Dose:

Cattle: 10 ml

Sheep: 5 ml

Lambs (under 10 kg bodyweight or 1 month of age): 2.5 ml

Administration: Apply a single dose with the special 'Squeeze 'n' Pour' dispenser pack or the Fly & Lice Spot On Applicator on one spot on the mid-line of the back at the shoulders as directed on 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 week later.

Flies on cattle: To control biting and non-biting flies, 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. Treatment for fly control should not be repeated within four weeks.

Ticks on sheep: Application to the mid-point of the shoulders will provide useful control of ticks attaching to animals of all ages, for up to 6 weeks 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 Spot On applied to the skin of the animal.

When using the Fly & Lice Spot On applicator application to the skin can be achieved by inserting the T bar to separate the fleece and penetrate down to the skin level before squeezing the applicator handle.

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.

Lice and ticks on lambs: Application to the mid-point of the shoulders will provide useful control of ticks for up to 6 weeks after treatment, and will reduce the incidence of biting lice over a 4-6 week period after treatment.

4.10 Overdose (symptoms, emergency procedures, antidotes)

There are no specific recommendations in the case of overdosage.

4.11 Withdrawal periods

Cattle (meat) – 17 days
Cattle (milk) – zero hours
Sheep (meat) – 35 days

The product is contra-indicated for use in ewes producing milk for human consumption.

5. PHARMACOLOGICAL PROPERTIES

ATCvet code: QP53AC11

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 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 pesticidal activity.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Fractionated Coconut Oil

6.2 Incompatibilities

None known.

6.3 Shelf-life

Shelf-life of the veterinary medicinal product as packaged for sale: 5 years.

6.4 Special precautions for storage

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

Do not store above 25°C. Do not freeze.

6.5 Nature and composition of immediate packaging

250 and 500 ml natural high-density polyethylene bottle with internal graduated calibration chamber with white formaldehyde screw cap.

1 litre and 2.5 litre white high density polyethylene flexipack with white plastic screw cap

Not all pack sizes may be marketed.

6.6 Special precautions for the disposal of unused product or waste material, if any

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

Zoetis UK Limited
1st Floor, Birchwood Building
Springfield Drive
Leatherhead
Surrey
KT22 7LP

8. MARKETING AUTHORISATION NUMBER

Vm 42058/4096

9. DATE OF FIRST AUTHORISATION

21 December 1984

10. DATE OF REVISION OF THE TEXT

August 2020

Approved 28 August 2020



Hunter.