Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Spotinor 10 mg/ml Spot-on Solution for cattle and sheep.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains

Active substance:
Deltamethrin 10 mg

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Spot-On Solution.
A clear pale gold oily liquid.

4 CLINICAL PARTICULARS

4.1 Target Species

Cattle and Sheep.

4.2 Indications for use, specifying the target species

For the treatment and prevention of infestations by lice and flies on cattle; ticks, lice, keds and established blowfly strike on sheep and lice and ticks on lambs.

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* in beef and dairy cattle. Also as an aid in the treatment and prevention of infestations of both biting and nuisance flies including *Haematobia irritans, Stomoxys calcitrans, Musca* species and *Hydrotaea irritans.*

On sheep: For the treatment and prevention of infestations by ticks *Ixodes ricinus* and by lice (*Linognathus ovillus, Bovicola ovis*), keds (*Melophagus ovinus*) and established blowfly strike (usually *Lucilia spp*).

On lambs: For the treatment and prevention of infestations by ticks *Ixodes ricinus* and by lice *Bovicola ovis*.

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

To avoid resistance, the product should only be used if the susceptibility of the local fly population to the active substance is assured.
Cases of resistance to deltamethrin have been reported in stinging and nuisance flies in cattle and lice in sheep.
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, or lack of calibration of the dosing device.

If clinical signs do not resolve following treatment, the diagnosis should be revised.

4.5 Special precautions for use

(i) Special precautions for use in animals

The product is for external use only.
Do not apply on or near the animal's eyes and mucous membranes.
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 product to the animal

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 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.

To the physician:
Advice on clinical management is available from the National Poisons Information Service.

(iii) Other Precautions
Deltamethrin is very toxic to dung fauna, aquatic organisms and honey bees, is persistent in soils and may accumulate in sediments.
The risk to aquatic ecosystems and dung fauna can be reduced by avoiding too frequent and repeated use of deltamethrin (and other synthetic pyrethroids) in cattle and sheep, e.g. by using a single treatment per year on the same pasture.
The risk to aquatic ecosystems will be further reduced by keeping treated cattle away from water bodies for four weeks after treatment.

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.

Use of the product during pregnancy and lactation in cows and ewes must be according to the benefit/risk assessment made 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.

4.9 Amounts to be administered and administration route

For external use.

Dose:
Cattle: 100 mg of deltamethrin per animal corresponding to 10 ml of product.
Sheep: 50 mg of deltamethrin per animal corresponding to 5 ml of product
Lambs (under 10 kg bodyweight or 1 month of age): 25 mg of deltamethrin per animal corresponding to 2.5 ml of product.

Administration: Apply a single dose with the special 'Squeeze 'n' Pour' dispenser pack or the Spot-On Applicator in one spot on the mid-line of the back at the shoulders. 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.

Flies on cattle: For the treatment and prevention of infestations by biting and non-biting flies. Where horn-flies predominate, treatment and prevention of infestations can be expected for 4 - 8 weeks. Treatment for flies should not be repeated within four weeks.

Ticks on sheep: Application to the mid-point of the shoulders will provide useful treatment and prevention of infestations by 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.
It is advisable to:
- treat shortly after shearing (animals with short fleece),
- keep treated sheep separated from untreated sheep to avoid re-infestation.

N.B. For treatment and prevention of infestations by ticks, keds and lice on sheep, the fleece should be parted and the Spot-On 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.

Lice and ticks on lambs: Application to the mid-point of the shoulders will provide useful treatment and prevention of infestations by 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), if necessary

Some adverse effects have been seen following overdose. These include paraesthesia and irritation in cattle, as well as intermittent or attempted urination in young lambs. 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 authorised for use in ewes producing milk for human consumption.

5 PHARMACOLOGICAL or IMMUNOLOGICAL 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 properties

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

5.3 Environmental properties

Deltamethrin has the potential to adversely affect non-target organisms, both in water and in dung. Following treatment, excretion of potentially toxic levels of deltamethrin may take place over a period of 4 weeks. Faeces containing deltamethrin excreted onto pasture by treated animals may reduce the abundance of dung feeding organisms which may impact on the dung degradation.

Deltamethrin is very toxic to dung fauna, aquatic organisms and honey bees, is persistent in soils and may accumulate in sediments.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Medium-chain Triglycerides

6.2 Incompatibilities

None known.

6.3 Shelf-life

Shelf-life of the veterinary medicinal product as packaged for sale: 3 years.
Shelf-life after first opening the immediate packaging: 6 months

6.4 Special precautions for storage

Store the dispenser bottle in the outer carton in order to protect from light.
Do not freeze.

6.5 Nature and composition of immediate packaging

250 and 500 ml clear high-density polyethylene bottle with internal graduated calibration chamber and a white screw polypropylene cap.

1 litre and 2.5 litre white high density polyethylene back pack for use with a suitable dosing device and a white screw polypropylene cap.

Not all pack sizes may be marketed.

6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials

Dangerous to fish and other aquatic organisms. 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

Norbrook Laboratories Ltd
Station Works
Newry
BT35 6JP
Co. Down
Northern Ireland

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10999/171/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 5th September 2014

10 DATE OF REVISION OF THE TEXT

October 2015.