PARTICULARS TO APPEAR ON THE OUTER PACKAGE {CARTON}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Spotinor 10 mg/ml Spot-on Solution

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains: 10mg Deltamethrin

3. PACKAGE SIZE

250 ml, 500 ml, 2 x 500 ml, 1 Litre, and 2.5 Litre.

4. TARGET SPECIES

Cattle and sheep.

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Spot-on use

7. WITHDRAWAL PERIODS

Withdrawal period:

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.

8. EXPIRY DATE

EXP: {mm/yyyy}
Shelf-life after first opening the container: 6 months
Once opened, use by:…….

9. SPECIAL STORAGE PRECAUTIONS

Store below 25 °C
Do not freeze.

Keep the dispenser bottle in the outer carton in order to protect from light.

10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”

Read the package leaflet before use.

11. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

Norbrook Laboratories Limited

14. MARKETING AUTHORISATION NUMBER

Vm 02000/4381

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE {LABEL}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Spotinor 10 mg/ml Spot-on Solution

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains: 10mg Deltamethrin

3. TARGET SPECIES

Cattle and sheep.

4. ROUTES OF ADMINISTRATION

Spot-on use
Read the package leaflet before use.

5. WITHDRAWAL PERIODS

Withdrawal period:

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.

6. EXPIRY DATE

EXP. {mm/yyyy}
Shelf-life after first opening the container: 6 months
Once opened use by…

7. SPECIAL STORAGE PRECAUTIONS

Store below 25 °C
Do not freeze.
Keep the dispenser bottle in the outer carton in order to protect from light

8. NAME OF THE MARKETING AUTHORISATION HOLDER

Norbrook Laboratories Limited

9. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

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

2. Composition

Each ml contains:

Active substance
Deltamethrin 10 mg

A clear, pale gold oily liquid.

3. Target species

Cattle and sheep.

4. Indications for use

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*.

5. Contraindications

Do not use on convalescent or sick animals.
Do not use in cases of hypersensitivity to the active substance or to any of the excipients.

6. Special warnings

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

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
People with hypersensitivity to deltamethrin or medium-chain triglycerides should avoid contact with the veterinary medicinal product.
Personal protective equipment consisting of waterproof apron, boots and impervious gloves should be worn when handling the veterinary medicinal product.
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 and show the package leaflet or the label to the physician.
In case of accidental ingestion, wash out mouth immediately with plenty of water and seek medical advice and show the package leaflet or the label 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.
To the physician: Advice on clinical management is available from the National Poisons Information Service.

Special precautions for the protection of the environment:
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 only 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.

Other precautions:
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.

Pregnancy and lactation:
The safety of the veterinary medicinal product has not been established during pregnancy and lactation.
Laboratory studies in rats and rabbits have not produced any evidence of teratogenic or embryotoxic effects.
Use only according to a benefit/risk assessment by the responsible veterinarian.

Interaction with other medicinal products and other forms of interaction:
Do not use with any other insecticide or acaricide. The toxicity of deltamethrin is enhanced in combination with organophosphorous compounds, in particular.

Overdose:
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.

Major incompatibilities:
None Known

7. Adverse events

Target species: Cattle, Sheep.

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Squamosis (scaly skin)[1,2], Pruritus (Itching)[1,2]; Discomfort[1] Lacrimation[2]

[1] Minor; may occur within 48 hours after treatment – short term and is not detrimental to the animal.
[2] Observed in cattle only.

Reporting adverse events is important. It allows continuous safety monitoring of a product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing

authorisation holder using the contact details at the end of this leaflet, or via your national reporting system at:

Website: https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine

e-mail: adverse.events@vmd.gov.uk

8. Dosage for each species, routes and method of administration

Spot-on use.
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 treatment and prevention of infestations by biting and non-biting flies. Where horn-flies predominate, good 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.

9. Advice on correct administration

For treatment and prevention of infestations by ticks, keds and lice on sheep, the fleece should be parted and 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.

10. Withdrawal periods

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.

11. Special storage precautions

Keep out of the sight and reach of children.

Store below 25^{o}C.
Do not freeze.

Keep the dispenser bottle in the outer carton in order to protect from light.

Do not use this veterinary medicinal product after the expiry date which is stated on the carton or bottle label after Exp. The expiry date refers to the last day of that month.

Shelf-life after first opening the immediate packaging: 6 months

12. Special precautions for disposal

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

This veterinary medicinal product should not enter water courses as Deltamethrin may be dangerous to 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 applicable national collection systems. These measures should help to protect the environment.
Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

Vm 02000/4381

250 ml, 1 x 500 ml and 2 x 500 ml clear high-density polyethylene bottle with internal graduated calibration chamber and a white screw polypropylene cap in a cardboard box.

1 litre and 2.5 litre white high-density polyethylene backpack for use with a suitable dosing device and a white screw polypropylene cap in a cardboard box.

Not all pack sizes may be marketed.

15. PID link (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

16. Contact details

Marketing authorisation holder and manufacturer responsible for batch release and contact details to report suspected adverse reactions:

Norbrook Laboratories Limited
Station Works
Camlough Road
Newry
Co. Down
BT35 6JP
Northern Ireland
Tel: +44 (0)28 3026 4435
E-mail: phvdept@norbrook.co.uk

17. Other information

For animal treatment only

POM-VPS

Gavin Hall

Approved: 24 September 2026