

ANNEX III
LABELLING AND PACKAGE LEAFLET

A. LABELLING

**PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE
{Label}****1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

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

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:

Active substance

Deltamethrin 10 mg

3. PHARMACEUTICAL FORM

Spot-On Solution

4. PACKAGE SIZE

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

5. TARGET SPECIES

Cattle
Sheep

6. INDICATION(S)

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. For further details please refer to the package leaflet.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.

8. 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.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP: dd/mm/yyyy

Shelf-life after first opening the container: 6 months

Once opened, use by:.....

11. SPECIAL STORAGE CONDITIONS

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

Do not freeze.

Store below 25°C.

12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: read package leaflet

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

For animal treatment only

POM- VPS

To be supplied only on Veterinary Prescription

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Norbrook Laboratories Limited
Station Works
Camlough Road
Newry
Co. Down
BT35 6JP
Northern Ireland

16. MARKETING AUTHORISATION NUMBER(S)

Vm 02000/4381

17. MANUFACTURER'S BATCH NUMBER

BN:

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

{Carton}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:

Active substance

Deltamethrin 10 mg

3. PHARMACEUTICAL FORM

Spot-On Solution

4. PACKAGE SIZE

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

5. TARGET SPECIES

Cattle
Sheep

6. INDICATION(S)

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. For further details please refer to the package leaflet.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.

Dosing:

Cattle: 10ml

Sheep: 5ml

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

8. 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.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP: dd/mm/yyyy

Shelf-life after first opening the container: 6 months

Once opened, use by:.....

11. SPECIAL STORAGE CONDITIONS

<Store the dispenser bottle in the outer carton in order to protect from light.>

Do not freeze.

Store below 25°C.

12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: read package leaflet

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

For animal treatment only

POM- VPS

To be supplied only on Veterinary Prescription

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Norbrook Laboratories Limited
Station Works
Camlough Road
Newry
Co. Down
BT35 6JP
Northern Ireland

Distributed by:

Norbrook Laboratories Limited
Carnbane Industrial Estate
Newry
BT35 6QQ
Co Down
Northern Ireland

16. MARKETING AUTHORISATION NUMBER(S)

Vm 02000/4381

17. MANUFACTURER'S BATCH NUMBER

BN:

B. PACKAGE LEAFLET

PACKAGE LEAFLET

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

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing Authorisation holder
Norbrook Laboratories Limited
Station Works
Newry
Co. Down
BT35 6JP
Northern Ireland

Manufacturer responsible for batch release:
Norbrook Laboratories Limited
Station Works
Newry
Co. Down
BT35 6JP
Northern Ireland

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

Each ml contains:

Active substance
Deltamethrin 10 mg

A clear, pale gold oily liquid.

4. INDICATION(S)

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 in ewes producing milk for human consumption.

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.

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.

6. ADVERSE REACTIONS

Squamosis and pruritus have been very rarely seen in cattle during the 48 hours after treatment.

The frequency of adverse reactions is defined using the following convention:

- very rare (less than 1 animal in 10,000 animals treated, including isolated reports)

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 inform your veterinary surgeon.

7. TARGET SPECIES

Cattle

Sheep

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

For external use.

Spot-on application.

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 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.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

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

Do not freeze. Store below 25°C.

Do not use this veterinary medicinal product after the expiry date which is stated on the carton or bottle label after "EXP".

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

12. SPECIAL WARNING(S)

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. 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:

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.

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 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.

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 (symptoms, emergency procedures, antidotes):

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

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

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.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

October 2022

15. OTHER INFORMATION

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.

Package Information

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 back pack for use with a suitable dosing device and a white screw polypropylene cap in a cardboard box.

Not all pack sizes may be marketed.

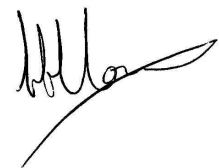
POM- VPS

To be supplied only on Veterinary Prescription

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

Distributed by:

Norbrook Laboratories Limited
Carnbane Industrial Estate
Newry
BT35 6QQ
Co Down
Northern Ireland



Approved 28 October 2022