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

Authorised

- Deltamethrin

Product identification

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

Active substance:
Deltamethrin

Target species:
Cattle
Sheep

Route of administration:
Spot-on use

Product details

Active substance and strength:
Deltamethrin
10.00 milligram(s) / 1.00 millilitre(s)

Pharmaceutical form:
Spot-on solution

Withdrawal period by route of administration:

Spot-on use:

- **Cattle**
  - Meat and offal. 17 day
  - Milk. 0 hour
- **Sheep**
  - Meat and offal. 35 day
  - Milk. no withdrawal period

Not authorised for use in ewes producing milk for human consumption.

Anatomical therapeutic chemical veterinary (ATCvet) codes:
QP53AC11

Legal status of supply:
Veterinary medicinal product subject to veterinary prescription

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Authorisation status:
Valid

Authorised in:
Denmark

Available in:
Denmark

Package description:
250 ml clear high-density polyethylene bottle with internal graduated calibration chamber and awhite screw polypropylene cap in a cardboard box.
1 x 500 ml clear high-density polyethylene bottle with internal graduated calibration chamber and awhite screw polypropylene cap in a cardboard box.
2 x 500 ml clear high-density polyethylene bottle with internal graduated calibration chamber and awhite screw polypropylene cap in a cardboard box.
1 litre white high density polyethylene back pack for use with a suitable dosing device and a white screwpolypropylene cap in a cardboard box.

2.5 litre white high density polyethylene back pack for use with a suitable dosing device and a white screwpolypropylene cap in a cardboard box.

Additional information

Entitlement type:
Marketing Authorisation

Legal basis of product authorisation:
Generic application (Article 13(1) of Directive No 2001/82/EC)

Marketing authorisation holder:
Norbrook Laboratories (Ireland) Limited

Marketing authorisation date:
24/09/2014

Manufacturing sites for batch release:
Norbrook Manufacturing Limited
Norbrook Laboratories Limited

Responsible authority:
Danish Medicines Agency

Authorisation number:
52375

Date of authorisation status change:
24/09/2014

Reference member state:
Ireland

Procedure number:
IE/V/0544/001

Concerned member states:
Austria Belgium Bulgaria Cyprus Denmark Estonia Finland France Greece Hungary Italy Latvia Lithuania Luxembourg Malta Poland Portugal Romania

Spain Sweden United Kingdom (Northern Ireland)

To consult adverse reactions on veterinary medicinal products please go to www.adrreports.eu/vet

Documents

Summary of Product Characteristics

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Combined File of all Documents