SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Dectospot 10 mg/ml Spot-on Solution for Cattle and Sheep

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance:

Deltamethrin 10.0 mg/ml

Excipients:

Qualitative composition of excipients and other constituents
Triglycerides, medium chain

A clear pale gold oily liquid

3. CLINICAL INFORMATION

3.1 Target species

Cattle and sheep.

3.2 Indications for use for each target species

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*.

3.3 Contraindications

None.

3.4 Special warnings

None.

3.5 Special precautions for use

Special precautions for safe use in the target species:
Care should be taken to avoid inaccurate dosing, misadministration or too frequent and repeated use of ectoparasiticides from the same class over an extended period of time as these practices increase the risk of development of resistance and could ultimately result in ineffective therapy.

For external use only.

Special precautions to be taken by the person administering the veterinary medicinal product to animals

Personal protective equipment consisting of waterproof apron and boots and impervious gloves should be worn when either applying the veterinary medicinal 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 veterinary medicinal 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 and show the package leaflet or the label to the physician.
Do not smoke, drink or eat while handling the veterinary medicinal product.

This veterinary medicinal product contains deltamethrin which may produce tingling, itchiness and blotchy redness on exposed skin. If you feel unwell after working with this veterinary medicinal product, consult your doctor and show this label. Advice to medical practitioners: 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 preventing treated sheep from entering watercourses for one hour immediately after treatment.

3.6 Adverse events

Cattle:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Signs of discomfort[1]

[1]Observed within 48 hours after treatment.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy and lactation:

No special precautions are recommended.

3.8 Interaction with other medicinal products and other forms of interaction

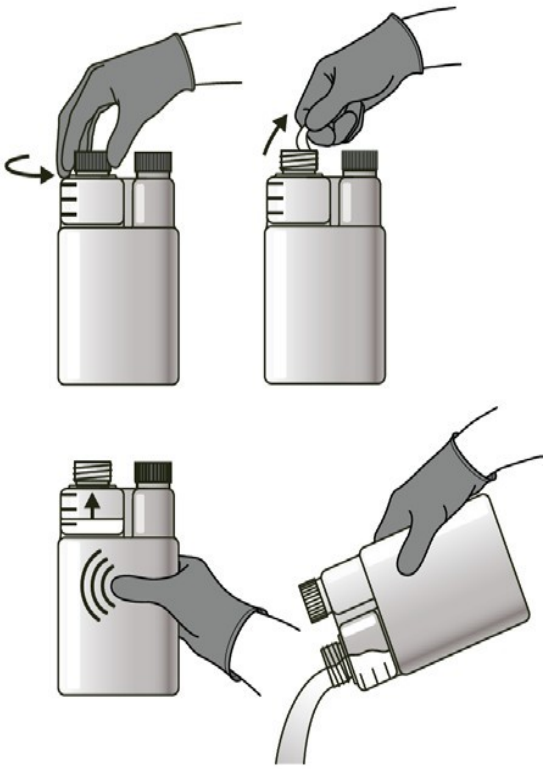
Some organo-phosphorous insecticides can reduce metabolism rate and thus enhance deltamethrin toxicity. Do not mix any other insecticide or acaricide with Dectospot Spot-on Solution.

3.9 Administration routes and dosage

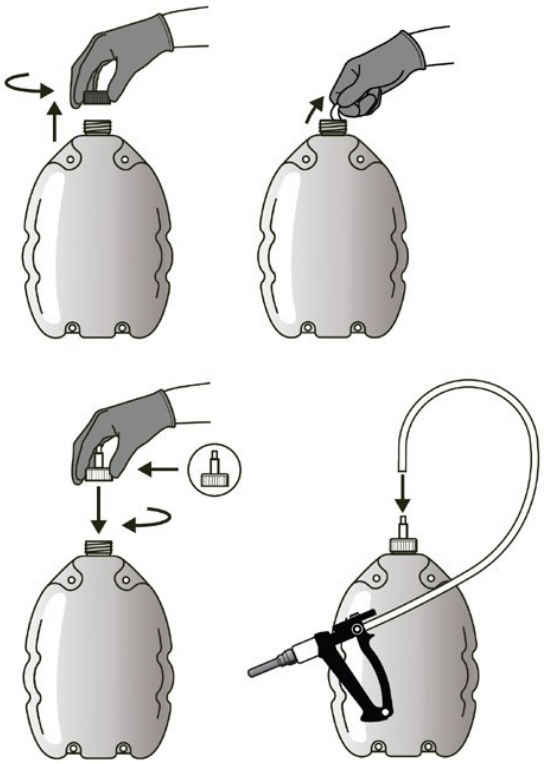
The product should be applied using an appropriate application device:
- For the 250ml and 500ml presentations a graduated chamber attached to the container is used.
- For the 1 litre and 2.5 litre presentations it is recommended to use an appropriate applicator.

The recommended use of the application devices is illustrated below.

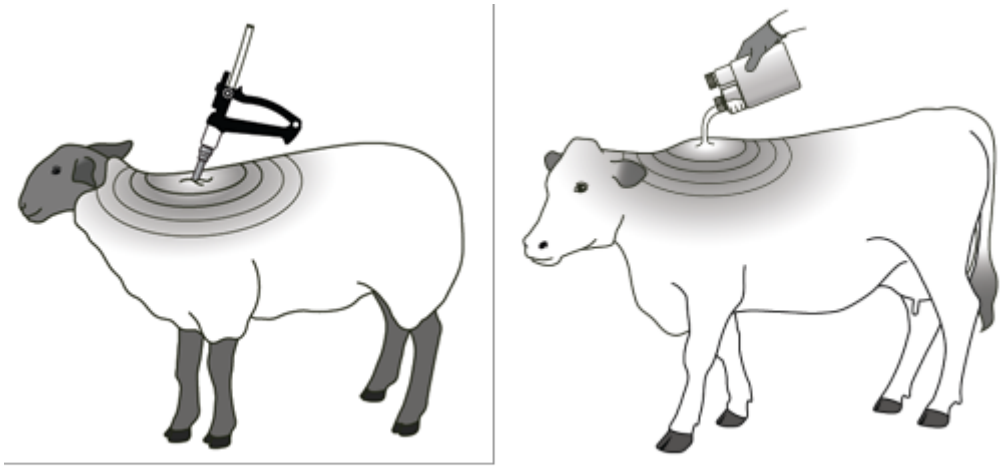
1.Use of the graduated chamber on the 250ml and 500 ml containers:



2.Attaching the 1 and 2.5 litre containers to the recommended applicator:



Dose:
Cattle: 10 ml
Sheep: 5ml
Lambs (under 10 kg bodyweight or 1 month of age): 2.5ml
Administration: Apply a single dose with the special dispenser pack or the Dectospot 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 weeks 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 Dectospot 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.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

There are no specific recommendations in the case of overdosage.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 Withdrawal periods

Cattle (meat and offal): 17 days
Cattle (milk): zero hours
Sheep (meat and offal): 35 days

This product is not authorised for use in ewes producing milk for human consumption.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code:

QP53AC11

4.2 Pharmacodynamics

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.

4.3 Pharmacokinetics

The precise mode of insecticidal activity of pyrethoids 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.

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 2 to 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.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

5.2 Shelf life

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

5.3 Special precautions for storage

The veterinary medicinal product does not require any special temperature storage conditions. Keep the container in the outer carton in order to protect from light.
Store in tightly closed original container away from food, drink and animal feeding stuffs.

5.4 Nature and composition of immediate packaging

Carton containing one 250 or 500 ml natural high-density polyethylene bottle with internal graduated calibration chamber with black plastic heat-sealed screw cap.

Carton containing one1 litre or one or two 2.5 litre white high density polyethylene flexipack with white polypropylene closures and induction heat-sealed screw-cap and spouted cap for connection to applicator.

Not all pack sizes may be marketed.

5.5 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

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

The veterinary medicinal product should not enter water courses as deltamethrin may be dangerous for fish and other aquatic organisms.
Do not contaminate ponds, waterways or ditches with the veterinary medicinal product or used container.
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 national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Bimeda Animal Health Limited

7. MARKETING AUTHORISATION NUMBER

Vm 50146/4023

8. DATE OF FIRST AUTHORISATION

27 March 2015

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

April 2026

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCT

Veterinary medicinal product subject to prescription.

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

Gavin Hall
Approved: 28 April 2026