

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF VETERINARY MEDICINAL PRODUCT

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

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

<u>Active Substance</u>	<u>mg/ml</u>
Deltamethrin	10.0

For the 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

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*.

4.3 Contraindications

None.

4.4 Special Warnings for Each 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.

4.5 Special Precautions for Use

i) Special precautions for use in animals

For external use only.

ii) Special Precautions to be taken by the person administering the product to animals

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. **Advice to medical practitioners:** 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 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.

4.6 Adverse Reactions (frequency and seriousness)

Minor signs of discomfort have been seen in some cattle during the 48 hours after treatment. This is of no long term detriment to the animal.

4.7 Use during pregnancy or lactation

No special precautions are recommended.

4.8 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.

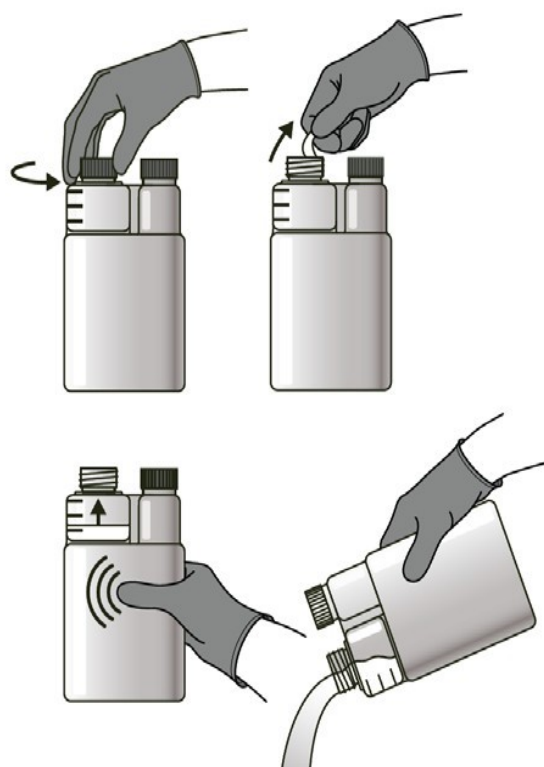
4.9 Amounts to be administered and administration route

The product should be applied using an appropriate application device:

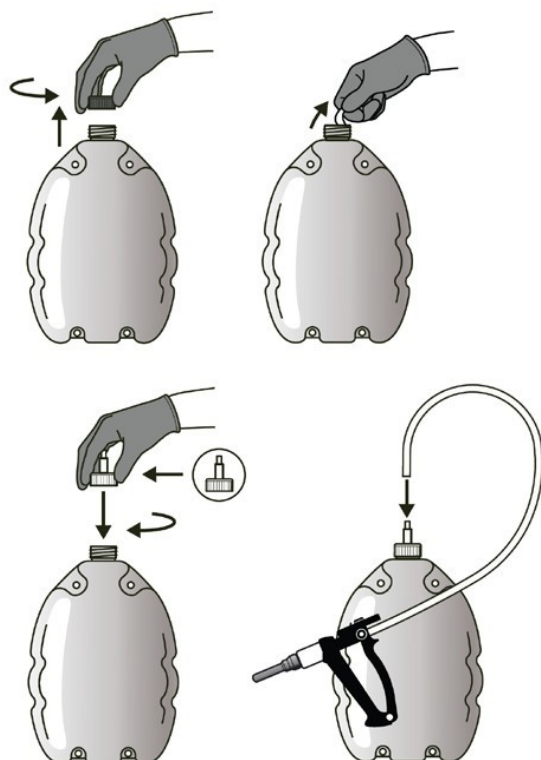
- For the 250ml and 500ml presentations a graduated chamber attached to the container is used.
- For the 1 litre and 2.5 litre presentations it is recommended to use an appropriate applicator.

The recommended use of the application devices is illustrated below.

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

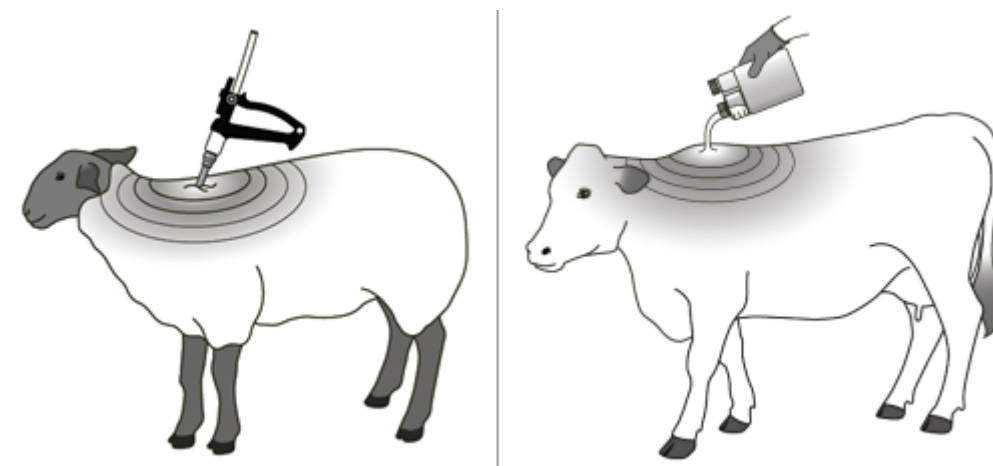


2. Attaching the 1 and 2.5 litre containers to the recommended applicator:



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.

4.10 Overdose

There are no specific recommendations in the case of overdosage.

4.11 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.

5. PHARMACOLOGICAL PROPERTIES

ATCvet code: QP53AC11

Pharmacotherapeutic group: Ectoparasiticides, insecticides and repellents.

Pyrethrins and pyrethroids.

5.1. Pharmacodynamic properties

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.

5.2. Pharmacokinetic properties

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 pesticidal activity.

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 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.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Triglycerides, medium chain

6.2 Major incompatibilities

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

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: 3 months

6.4 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.

6.5 Nature and Contents 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 one 1 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.

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

Dangerous to fish and other aquatic life. 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

Bimeda Animal Health Limited
2 / 3 / 4 Airton Close
Tallaght
Dublin 24
Ireland

8. MARKETING AUTHORISATION NUMBER

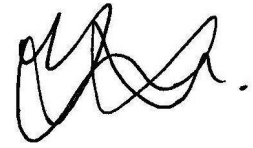
Vm 50146/4023

9. DATE OF FIRST AUTHORISATION

27 March 2015

10. DATE OF REVISION OF THE TEXT

February 2020

A handwritten signature in black ink, consisting of several loops and a final flourish.

Approved: 18 February 2020