1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Dectospot 10 mg/ml solution Pour-on pour bovins et ovins - FR, BE
Dectospot 10 mg/ml Pour-on-Lösung zum Übergießen für Rinder und Schafe - AT
Dectospot, 10 mg/ml kriipsulahus veistele ja lammastele - EE
Dectospot 10 mg/ml Pour-on Solution for Cattle and Sheep - IE
Dectospot 10 mg/ml soluzione pour-on per bovini e ovini - IT
Dectospot 10 mg/ml šķīdums uzliešanai uz muguras liellopiem un aitām - LV
Dectospot 10 mg/ml užpilamasis tirpalas galvijams ir avims - LT
Dectospot 10 mg/ml roztwór do polewania bydła i owiec - PL
Dectospot 10 mg/ml solução para unção contínua para bovinos e ovinos - PT
Dectospot 10 mg/ml soluție pour-on pentru bovine și ovine - RO
Dectospot 10 mg/ml Solución para unción dorsal continua para Bovino y Ovino - ES
Dectospot - DK
Dectospot vet 10 mg/ml kertavaleluliuos naudalle ja lampaalle - FI
Deltaspot vet 10 mg/ml pour-on, lösning för nötkreatur och får - SE

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains

Active Substance:
Deltamethrin 10.0 mg

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

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*. Also as an aid in the treatment and prevention of infestations by 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 for the treatment of established blowfly strike (usually *Lucilia* spp.).

On lambs: For the treatment and prevention of infestations by ticks *Ixodes ricinus* and by lice *Bovicola ovis*.

3.3 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.
Extra-label use of the veterinary medicinal 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.
Do not use in animals with extensive lesions of the skin.

3.4 Special warnings

The veterinary medicinal product will reduce the number of flies resting directly on the animal but it is not expected to eliminate all flies on a farm. Resistance to deltamethrin has been recognised and therefore the strategic use of the veterinary medicinal product should 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 veterinary medicinal product or lack of calibration of the dosing device.

Resistance to deltamethrin has been reported in stinging and nuisance flies in cattle and lice in sheep.

Unnecessary use of antiparasitics or use deviating from the instructions given in the SPC may increase the resistance selection pressure and lead to reduced efficacy. The decision to use the veterinary medicinal product should be based on confirmation of the parasitic species and burden, or of the risk of based on its epidemiological features, for each individual herd.
The use of this product should take into account local information about susceptibility of the target parasites, where available.
It is recommended to further investigate cases of suspected resistance, using an appropriate diagnostic method
Confirmed resistance should be reported to the marketing authorisation holder or to the competent authorities.

3.5 Special precautions for use

Special precautions for safe use in the target species:

The veterinary medicinal product is for external use only.
Do not apply on or near the animal’s eyes and mucous membranes as deltamethrin is an irritant.

Care should be taken to prevent animals grooming after administration of the veterinary medicinal product. Avoid use of the veterinary medicinal product during extremely hot weather and ensure animals have adequate access to water.

The veterinary medicinal 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.

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

People with known hypersensitivity to the active substance or to any of the excipients should avoid contact with the veterinary medicinal product.
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 re-use.
Wash splashes from skin immediately with soap and plenty of water.
Wash hands and exposed skin after handling this veterinary medicinal product.
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, seek medical advice immediately and show the package leaflet or the label to the physician.

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 and sheep:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Neurological signs (agitation[1] or prostration, tremors, abnormal movements) Skin disorders (application site skin squamosis, photosensitisation, pruritus)[2]

[1]General
[2]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 also the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

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 effects.
Use only according to the benefit/risk assessment by the responsible veterinarian.

3.8 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.

3.9 Administration routes and dosage

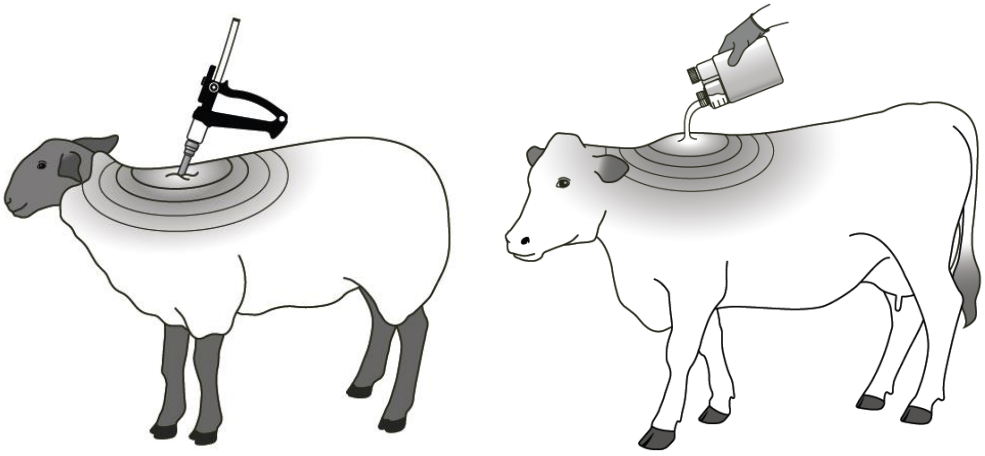
For external use. Pour-on application.
Underdosing could result in ineffective use and may favour resistance development.
To ensure a correct dosage, body weight should be determined as accurately as possible. If animals are to be treated collectively, reasonably homogeneous groups should be set up, and all animals of a group should be dosed at the rate corresponding to the heaviest one.
Dose:

Cattle: 100 mg of deltamethrin per animal, corresponding to 10 ml of the veterinary medicinal product.
Sheep: 50 mg of deltamethrin per animal, corresponding to 5 ml of veterinary medicinal product.
Lambs (under 10 kg bodyweight or 1 month of age): 25 mg of deltamethrin per animal, corresponding to 2.5 ml of veterinary medicinal product.

The veterinary medicinal product must be applied without dilution to the mid-point of the shoulders as shown in the diagrams below.

For treatment and prevention of infestations by ticks, keds and lice on sheep, the fleece should be parted and the veterinary medicinal product applied to the skin of the animal. For maximum effectiveness it is advisable to:

- treat shortly after shearing (animals with short fleece),
- keep treated sheep separated from untreated sheep to avoid re-infestation



The duration of protection against flies is maintained for 4–6 weeks.

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.

Keds and lice on sheep: One application will reduce the incidence of a biting louse or ked infestation over a 4–6 week period after treatment.

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.

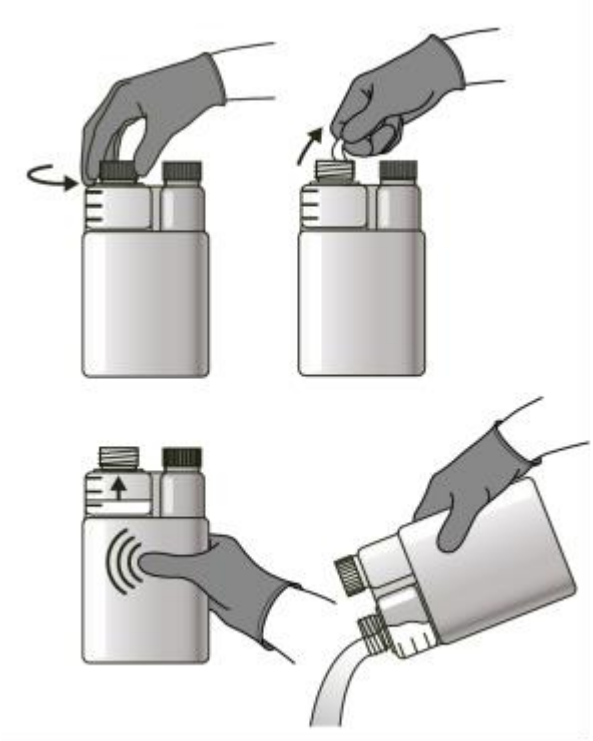
The influence of weather on the duration of efficacy has not been investigated.
The duration of the prevention period against *Musca* spp. may vary.

The product should be applied using an appropriate application device:
- For the 250 ml and 500 ml 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.

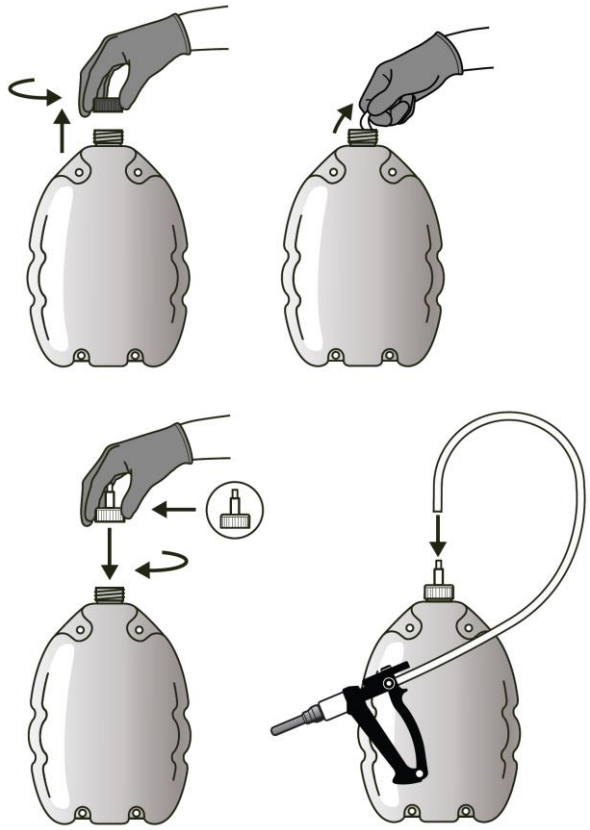
An appropriate applicator should comply with the following specifications :
- it should deliver doses of 5 ml and 10 ml.
- it should be supplied with a flexible hose of internal diameter between 6 mm and 12 mm.

The recommended use of the application devices is illustrated on the following diagrams.

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



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



3.10 Symptoms of overdose (and where applicable, emergency procedures and 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.

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: 18 days
Milk: zero hours

Sheep:
Meat and offal: 35 days
Milk: 24 hours

Due to the significant likelihood of cross-contamination of non-treated animals with this veterinary medicinal product due to grooming (licking), treated animals should be kept separate from non-treated animals throughout the maximum withdrawal period. Non-compliance with this recommendation may lead to residues in non-treated animals.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code:
QP53AC11

4.2 Pharmacodynamics

The deltamethrin molecule belongs to the family of synthetic pyrethroids. It is characterized by its insecticidal and acaricidal activity, acting by altering the permeability of the sodium channel molecule causing hyperarousal, followed by paralysis (knockdown), with tremors and mortality of parasites. Two physiological mechanisms are likely to contribute to deltamethrin-resistance: mutation of the molecular deltamethrin target or genomic selection for increased expression of mitochondrial oxidase and esterase enzymes.

4.3 Pharmacokinetics

After dermal application, deltamethrin is slightly absorbed through skin of cattle and sheep.
Pyrethroids are metabolised through oxidative and neurotoxic pathways.
The main route of excretion of the absorbed amount in the target animal is the faeces.

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.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

None known.

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

Store upright in the original container.
In order to protect from light keep the container in the outer carton.
Keep away from food, drink and animal feeding stuffs.

5.4 Nature and composition of immediate packaging

250 ml and 500 ml high density polyethylene flexipacks with twin neck dispenser, internal graduated calibration chamber and polypropylene heat-sealed screw cap.

1 litre and 2.5 litre high-density polyethylene flat bottom containers with polypropylene closures and induction heat-sealed wadding. A spouted cap is provided with the 1 litre and 2.5 litre presentations.

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 surface waters or ditches with the 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(S)

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: 17/12/2015

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

MM/YYYY

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database. (https://medicines.health.europa.eu/veterinary)