

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Deltafort 10 mg/ml Pour-on Solution

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains

Active substance:

Deltamethrin 10 mg

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Pour-on Solution

A slightly yellowish clear oily solution

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

Do not use in case of known hypersensitivity to the active substance or to any of the excipients.

Do not use on convalescent or sick animals.

4.4 Special warnings

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.

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.

The product will reduce the number of flies resting directly on the animal but it is not expected to eliminate all flies on the farm. The strategic use of the product should, therefore, be based on local and regional epidemiological information about the susceptibility of parasites, and used in association with other pest management methods.

4.5 Special precautions for use

Special precautions for use in animals

For external use only.

Do not apply on or near the animal's eyes or mucous membranes.

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.

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 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.

Application site reactions, including 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 common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports)

4.7 Use during pregnancy, lactation or lay

Laboratories studies (rat, rabbits) have not produced any evidence of teratogenic or embryotoxic effects.

No studies have been conducted with the product in pregnant cows and ewes.

The product can be used in cows and ewes during pregnancy and lactation, according to the benefit/risk assessment by the responsible veterinarian.

4.8 Interaction with other medicinal products and other forms of interaction

Do not use with any other insecticide or acaricide. Especially, in combination with organo-phosphorous compounds, the toxicity of deltamethrin is enhanced.

4.9 Amounts to be administered and administration route

For external use.

Dose:

Cattle: 100 mg of deltamethrin per animal corresponding to 10 ml

Sheep: 50 mg of deltamethrin per animal corresponding to 5ml

Lambs (under 10 kg bodyweight or 1 month of age): 25 mg of deltamethrin per animal corresponding to 2.5ml

Administration:

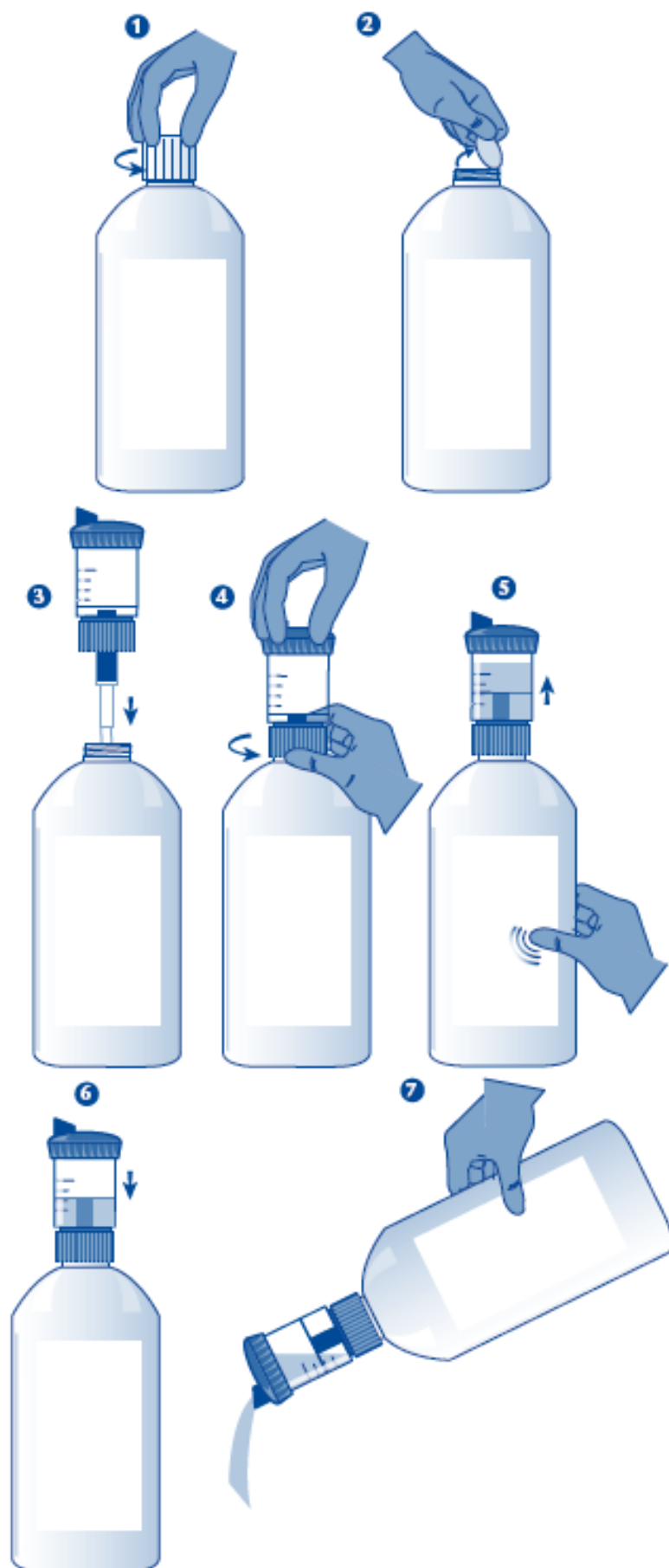
The product should be applied using an appropriate device :

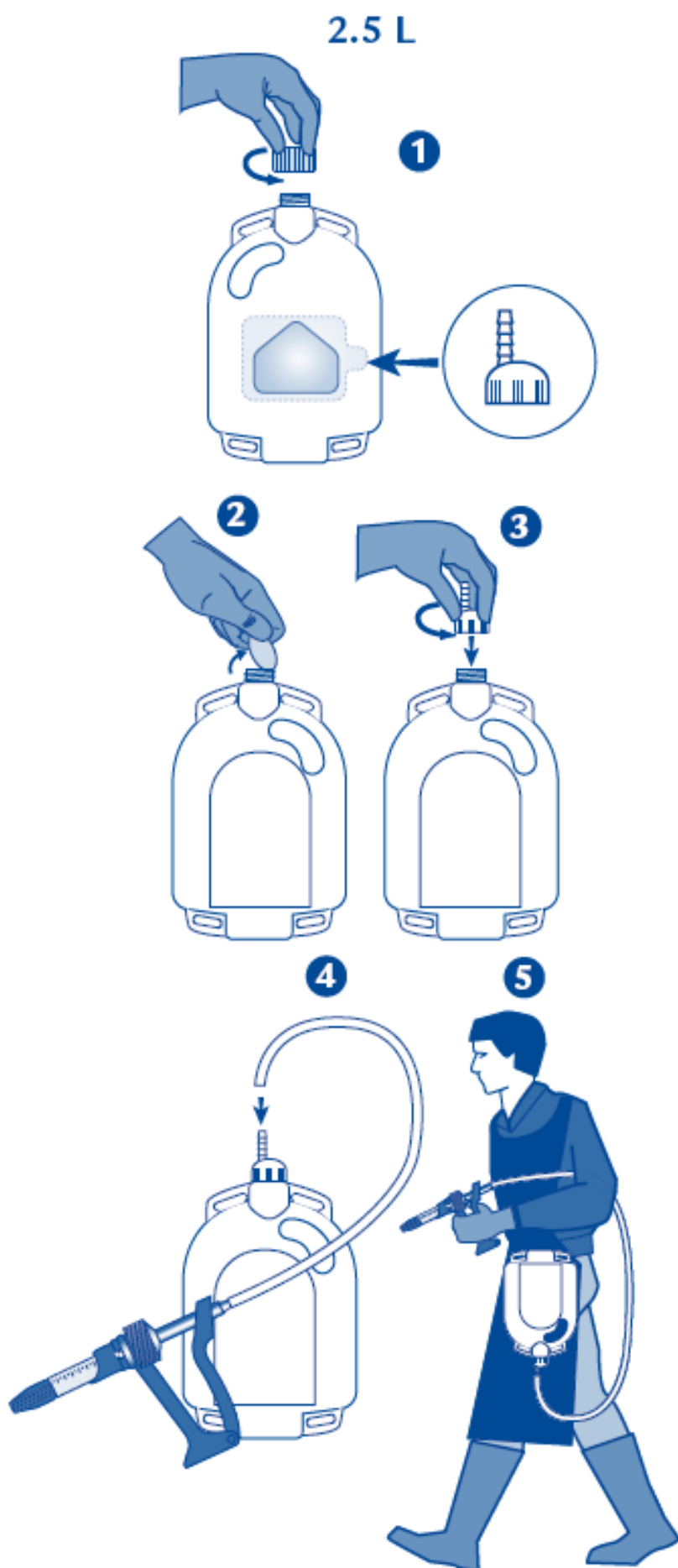
- for the 0.5L and 1L bottles, the product is supplied with a dosing cup
- for the 2.5L bottle and the 2.5L and 4.5L flexible pouches, it is recommended to use an appropriate dosing gun. The flexible pouches should be carried in an appropriate rucksack.

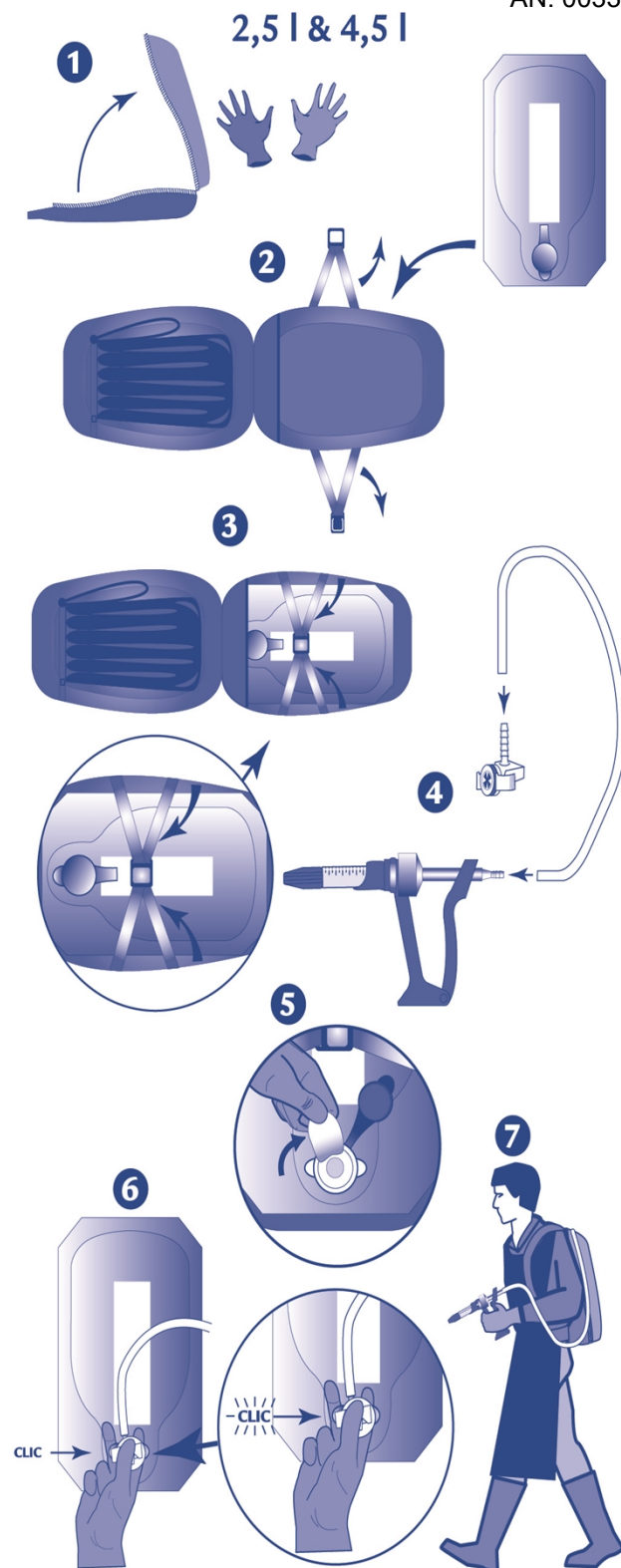
An appropriate applicator should comply with the following specifications:

- it should deliver doses of 2.5 mL, 5 mL and 10 mL.
- it should be supplied with a flexible “hose” of internal diameter between 10 mm and 14 mm.

500 ML & 1 L







Cattle : Apply a 10 mL dose using an appropriate applicator.

Sheep : Apply one 5 mL dose using an appropriate applicator.

Lambs : Apply one 2.5 mL dose using an appropriate applicator.

Application site :

Apply the product on 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: 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.

It is advisable to:

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

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.

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 (symptoms, emergency procedures, antidotes), if necessary

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.

4.11 Withdrawal period(s)

Cattle:

Meat and offal: 17 days
Milk: zero hours

Sheep:

Meat and offal: 35 days
Milk: zero hours

5. PHARMACOLOGICAL PROPERTIES

ATCvet code: QP53AC11

Pharmacotherapeutic group: pyrethroid ectoparasiticide for topical use.

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.

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.

Two physiological mechanisms are likely to contribute to deltamethrin-resistance: mutation of the molecular deltamethrin target in some and metabolic enzyme glutathione-S-transferases in some others.

5.2 Pharmacokinetic particulars

Environmental properties

Deltamethrin has the potential to adversely affect non-target organisms. Following treatment, deltamethrin is excreted in faeces. Deltamethrin excretion 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.

Deltamethrin is toxic to aquatic organisms and honey bees.

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: 5 years.

For bottles only: Shelf-life after first opening the immediate packaging: 1 year.

For pouches only: Shelf-life after first opening the immediate packaging: 2 years.

6.4 Special precautions for storage

This veterinary medicinal product does not require any special temperature storage conditions.

6.5 Nature and composition of immediate packaging

500 ml and 1 litre white high-density polyethylene bottle with a removable aluminium seal, a HDPE cap and a PP dosing device equipped with a measuring chamber delivering doses of 2.5 ml, 5 ml and 10 ml, placed in a carton box.

2.5 litre white high-density polyethylene bottle with a removable aluminium seal, a PP cap and a PP coupling vented cap.

2.5 litre or 4.5 litre multi-layer PET/aluminium/PA/PE flexible pouch with a PP cap and its specific coupling POM "E-lock", placed in a carton box.

Not all pack sizes may be marketed.

6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials 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

Virbac
1ère avenue 2065m LID
06516 Carros Cedex
France

8. MARKETING AUTHORISATION NUMBER

Vm 05653/4170

9. DATE OF FIRST AUTHORISATION

15 April 2013

10. DATE OF REVISION OF THE TEXT

August 2023



Approved: 17 August 2023