SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Deltanil 10 mg/ml Pour-on Solution for cattle and sheep

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
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 treatment and prevention of infestations by lice and flies on cattle; ticks, lice, keds and established blowfly strike on sheep and lice and ticks on lambs.

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*)
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*.

4.3 Contraindications

Do not use on convalescent or sick animals.
Do not use in cases of hypersensitivity to the active substance or any of the excipients.
Do not use in animals with extensive lesions of the skin.
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.

4.4 Special warnings <for each target species>

To avoid resistance, the product should only be used if the susceptibility of the local fly population to the active substance is assured. If clinical signs do not resolve following treatment, the diagnosis should be revised.
Cases of resistance to deltamethrin have been reported in stinging and nuisance flies in cattle and lice in sheep.
In countries with recognized resistance to deltamethrin the use of the product should ideally be based on results of susceptibility testing. Please, ask your veterinarian for further information.
The product will reduce the number of flies resting directly on the animal but it is not expected to eliminate all flies on a farm. The strategic use of the product should, therefore, 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 product, or lack of calibration of the dosing device.

4.5 Special precautions for use

Special precautions for use in animals

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

The product is for external use only.
Avoid contact with eyes and mucous membranes as Deltamethrin is an irritant.

Care should be taken to prevent licking of the product. Avoid use of the product during extremely hot weather and ensure animals have adequate access to water.

The 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

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 re-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, seek medical advice and show the package leaflet to the physician.
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, seek medical advice immediately and show the package leaflet or the label to the physician

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)

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

The safety of the veterinary medicinal product has not been established during pregnancy and lactation
Laboratories studies in rat and rabbits have not produced any evidence of teratogenic effects.
Use only according to a 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.

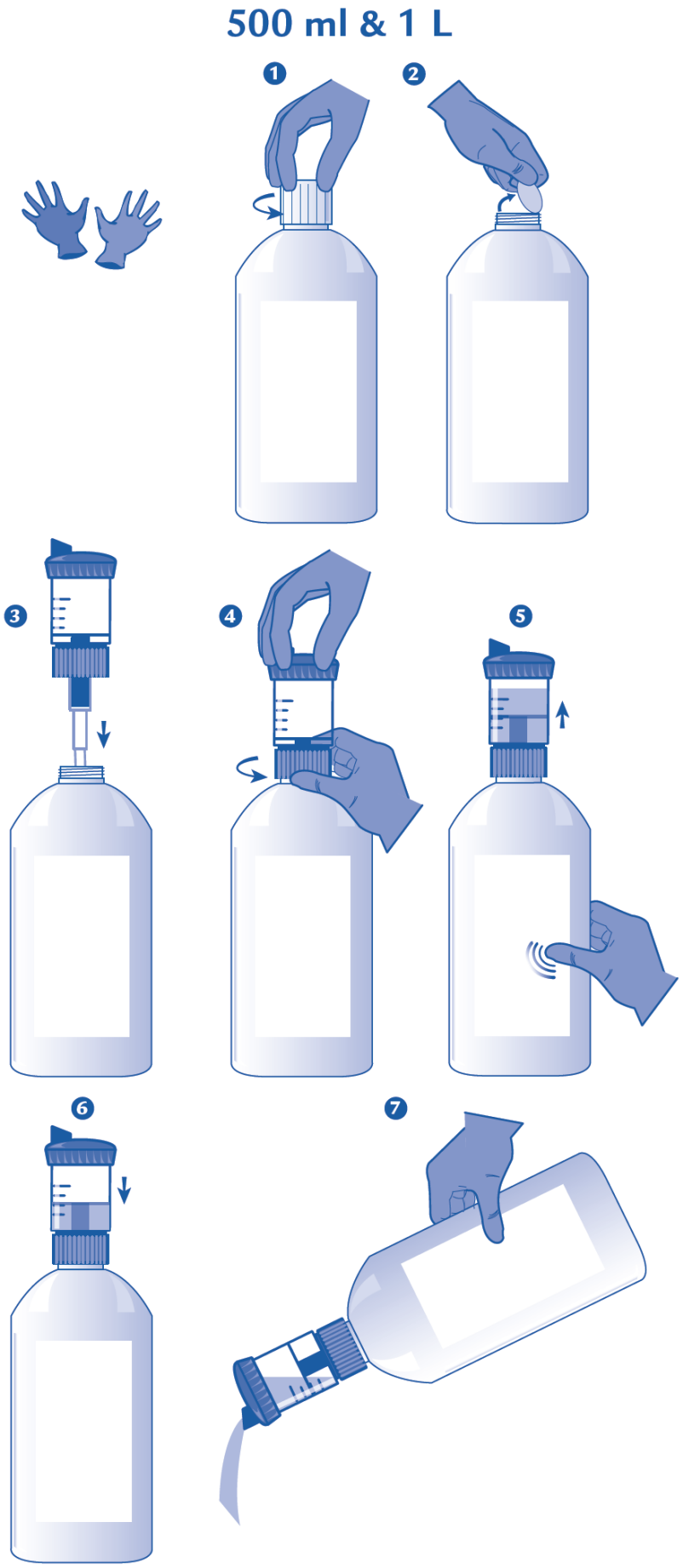
4.9 Amounts to be administered and administration route

For external use. Pour-on application

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

Administration:
The product should be applied using an appropriate device :
- for the 0.5 litre and 1 litre bottles, the product is supplied with a dosing cup
- for the 2.5 litre bottle and the 2.5 litre and 4.5 litre 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.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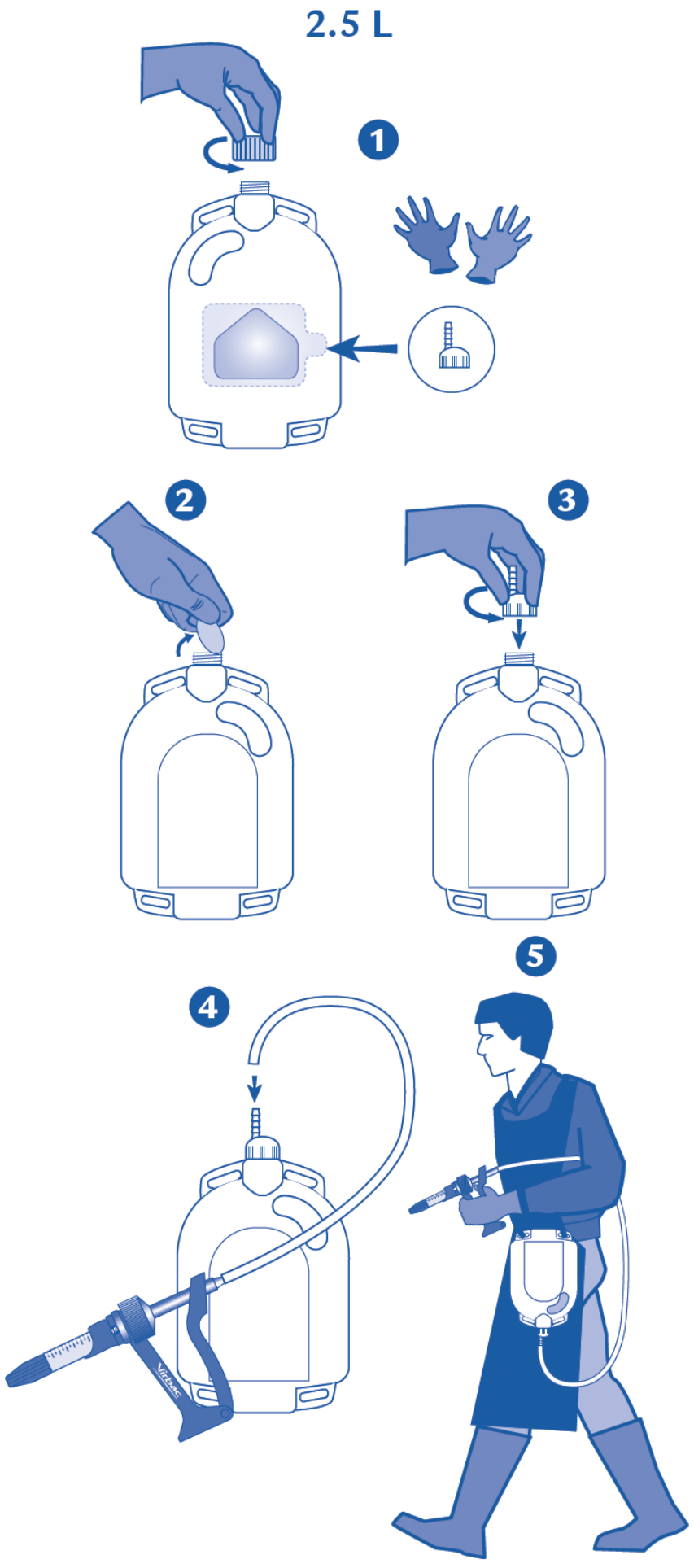
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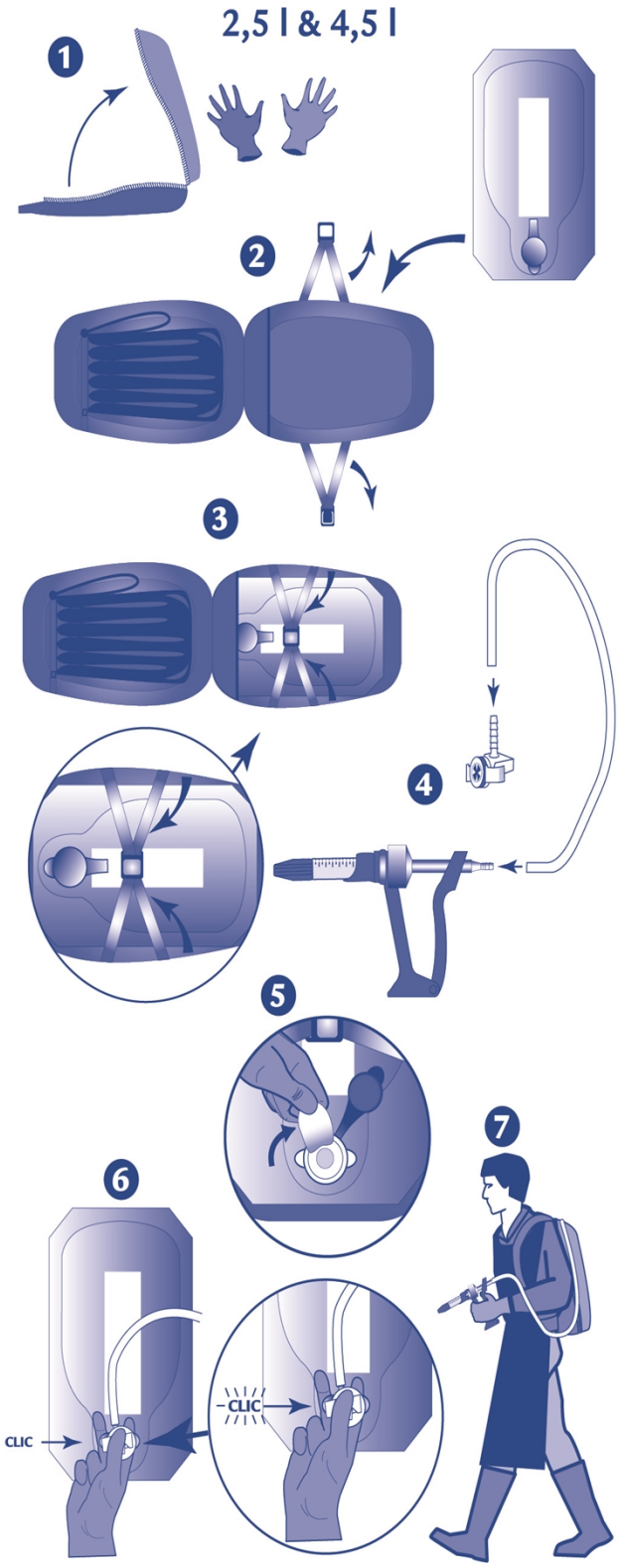

Cattle : Apply a 10 ml dose using an appropriate applicator.

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 along the mid-line of the back at the level of the shoulders.
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: Where horn-flies predominate, treatment and prevention of infestations can be expected for 4 - 8 weeks.

Ticks on sheep: Application to the mid-point of the shoulders will provide treatment and prevention of infestations by 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 treatment and prevention of infestations by ticks, keds and lice on sheep, the fleece should be parted and the product 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-line of the back at the level of the shoulders will provide treatment and prevention of infestations by 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

Pharmacotherapeutic group: Ectoparasiticide for topical use, including insecticides. Pyrethrins and pyrethroids.
ATCvet code: QP53AC11

5.1 Pharmacodynamic properties

Deltamethrin is a synthetic pyrethroid possessing insecticidal and acaricidal 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 ectoparasitic activity.

Two physiological mechanisms are likely to contribute to deltamethrin-resistance: mutation of the molecular deltamethrin target or through metabolic enzyme glutathione-S-transferases.

5.2 Pharmacokinetic particulars

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. 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 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: 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

Store in tightly closed original container away from food, drink and animal feeding stuffs

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 (Flexibag) 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

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.
The product should not enter water courses as this may be dangerous for fish and other aquatic organisms. Do not contaminate surface waters or ditches with the product or used container.
Deltamethrin has been shown to be persistent in soil.

7. MARKETING AUTHORISATION HOLDER

Virbac
1ère avenue - 2065m – L.I.D.
06516 Carros Cedex
France

8. MARKETING AUTHORISATION NUMBER

Vm 05653/5074

9. DATE OF FIRST AUTHORISATION

04 April 2014

10. DATE OF REVISION OF THE TEXT

November 2024

Approved: 08 March 2019