

**PARTICULARS TO APPEAR ON THE OUTER PACKAGE
PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE**

BOTTLES ; FLEXIBLE POUCHES

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. STATEMENT OF ACTIVE SUBSTANCES

Deltamethrin 10 mg/ml

3. PHARMACEUTICAL FORM

Pour-on Solution

4. PACKAGE SIZE

500 ml 'bottle'

1 l 'bottle'

2.5 l 'bottle'

2.5 l 'flexible pouch' (Flexibag)

4.5 l 'flexible pouch' (Flexibag)

5. TARGET SPECIES

Cattle and sheep.

6. INDICATION(S)

Read the package leaflet before use

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Pour-on use.

Read package leaflet before use.

8. WITHDRAWAL PERIOD

Withdrawal period

Cattle:

Meat and offal: 17 days

Milk: zero hours

Sheep:

Meat and offal: 35 days

Milk: zero hours

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}

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

Once opened use by...

11. SPECIAL STORAGE CONDITIONS

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

12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: read package leaflet.

13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

For animal treatment only.

14. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

VIRBAC

1ère avenue – 2065m – LID

06516 Carros Cedex

FRANCE

16. MARKETING AUTHORISATION NUMBER(S)

Vm 05653/4168

17. MANUFACTURER’S BATCH NUMBER

<Lot> {number}

PACKAGE LEAFLET:

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

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder and manufacturer responsible for batch release :

VIRBAC
1ère avenue – 2065m – LID
06516 Carros
FRANCE

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

3. STATEMENT OF THE ACTIVE SUBSTANCE (S) AND OTHER INGREDIENTS

Each ml contains:

Active substance:

Deltamethrin 10 mg

Slightly yellowish clear oily solution.

4. INDICATION(S)

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* on all ages of cattle including dairy cattle producing milk for human consumption. 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 of lice (*Linognathus ovillus*, *Bovicola ovis*) and 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 lice *Bovicola ovis*.

5. 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.

6. ADVERSE REACTIONS

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)

If you notice any side effects or other effects not already listed in this package leaflet, or you think that the medicine has not worked, please inform your veterinarian surgeon.

Alternatively you can report via your national reporting system {national system details}

7. TARGET SPECIES

Cattle and sheep.

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

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:

When using a multi-dose container, 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

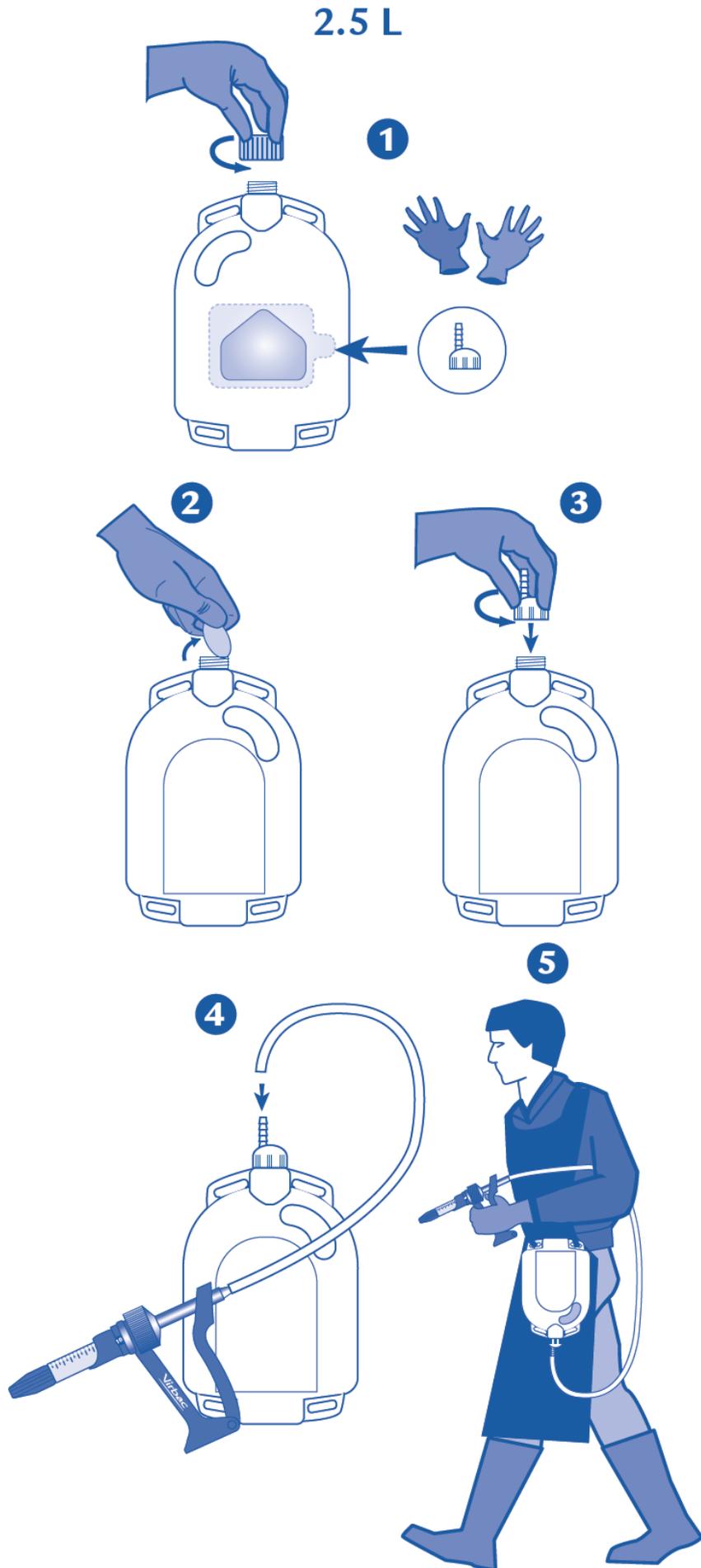
- for the 2.5 litre bottle and the 2.5 litre and 4.5 litre flexible pouches, it is recommended to use an appropriate dosing gun. The flexible pouches should be carried in an appropriate rucksack.

An appropriate applicator should comply with the following specifications :

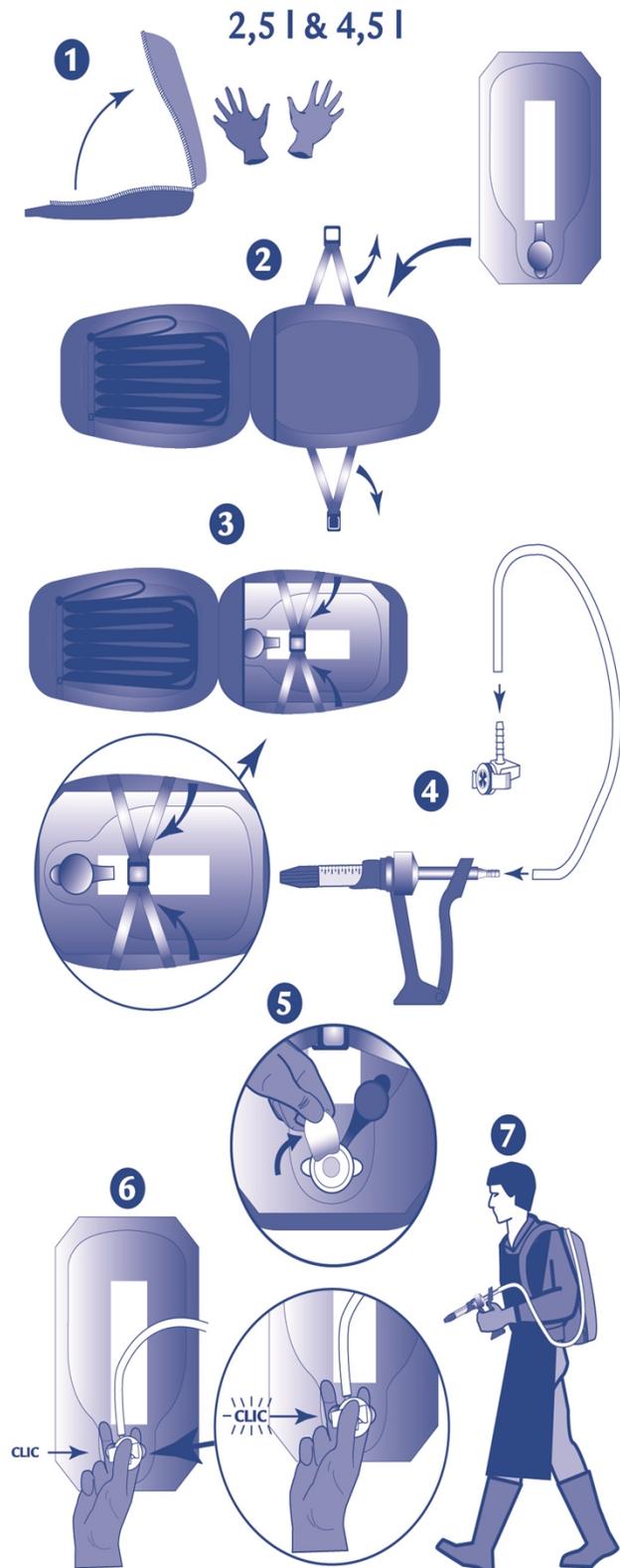
- it should deliver doses of 2.5 ml, 5 ml and 10 ml.
- it should be supplied with a flexible hose of internal diameter between 10 mm and 14 mm.

500 ml & 1 L





[in relevant cases, an additional step (under 5) should be included for the removal of the additional unviolability seal:]



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.

9. ADVICE ON CORRECT ADMINISTRATION

Application site :

Apply the product along the mid-line of the back at 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 along the mid-line of the back at 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.

10. WITHDRAWAL PERIOD

Cattle:

Meat and offal: 17 days

Milk: zero hours

Sheep:

Meat and offal: 35 days

Milk: zero hours

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

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

Do not use after the expiry date stated on the carton and bottle or pouch.

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

When the container is broached (opened) for the first time, using the in-use shelf-life which is specified on this package leaflet, the date on which any product remaining in the carton should be discarded should be worked out. This discard date should be written in the space provided.

12. SPECIAL WARNING(S)

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.

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.

Pregnancy, lactation or lay

The safety of the veterinary medicinal product has not been established during pregnancy and lactation

Laboratory 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.

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.

Overdose (symptoms, emergency procedures, 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.

Incompatibilities

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

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

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.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

15. OTHER INFORMATION

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.

500 ml and 1 litre bottle with a 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 bottle with a PP coupling vented cap.

2.5 litre or 4.5 litre flexible pouch (Flexibag) with a specific coupling POM "E-lock", placed in a carton box.

Not all pack sizes may be marketed.

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

Approved: 08 March 2019

