[Version 9, 03/2022] corr. 11/2022

ANNEX I

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

Excipients:

Qualitative composition of excipients and other constituents
Triglycerides medium-chain

Slightly yellowish clear oily solution.

3. CLINICAL INFORMATION

3.1 Target species

Cattle and sheep.

3.2 Indications for use for each 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*.

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.
Do not use in animals with extensive lesions of the skin.
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.

3.4 Special warnings

To avoid resistance, the veterinary medicinal 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 veterinary medicinal product should ideally be based on results of susceptibility testing. Please, ask your veterinarian for further information.
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. The strategic use of the veterinary medicinal 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 veterinary medicinal product, or lack of calibration of the dosing device.

3.5 Special precautions for use

Special precautions for safe use in the target species:

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

The veterinary medicinal 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 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 veterinary medicinal product or one of its components should avoid contact with the veterinary medicinal product.

Personal protective equipment consisting of protective clothing including waterproof apron and boots and impervious gloves should be worn 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 veterinary medicinal 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 immediately 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 / Sheep:

Very rare (< 1 animal/10,000 animals treated, including isolated reports):	Application site reactions[1] (e.g. application site squamosis, application site pruritus)

[1] Observed in cattle during the 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 the package leaflet for respective contact details.

3.7 Use during 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 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. Especially, in combination with organo-phosphorous compounds, the toxicity of deltamethrin is enhanced.

3.9 Administration routes and dosage

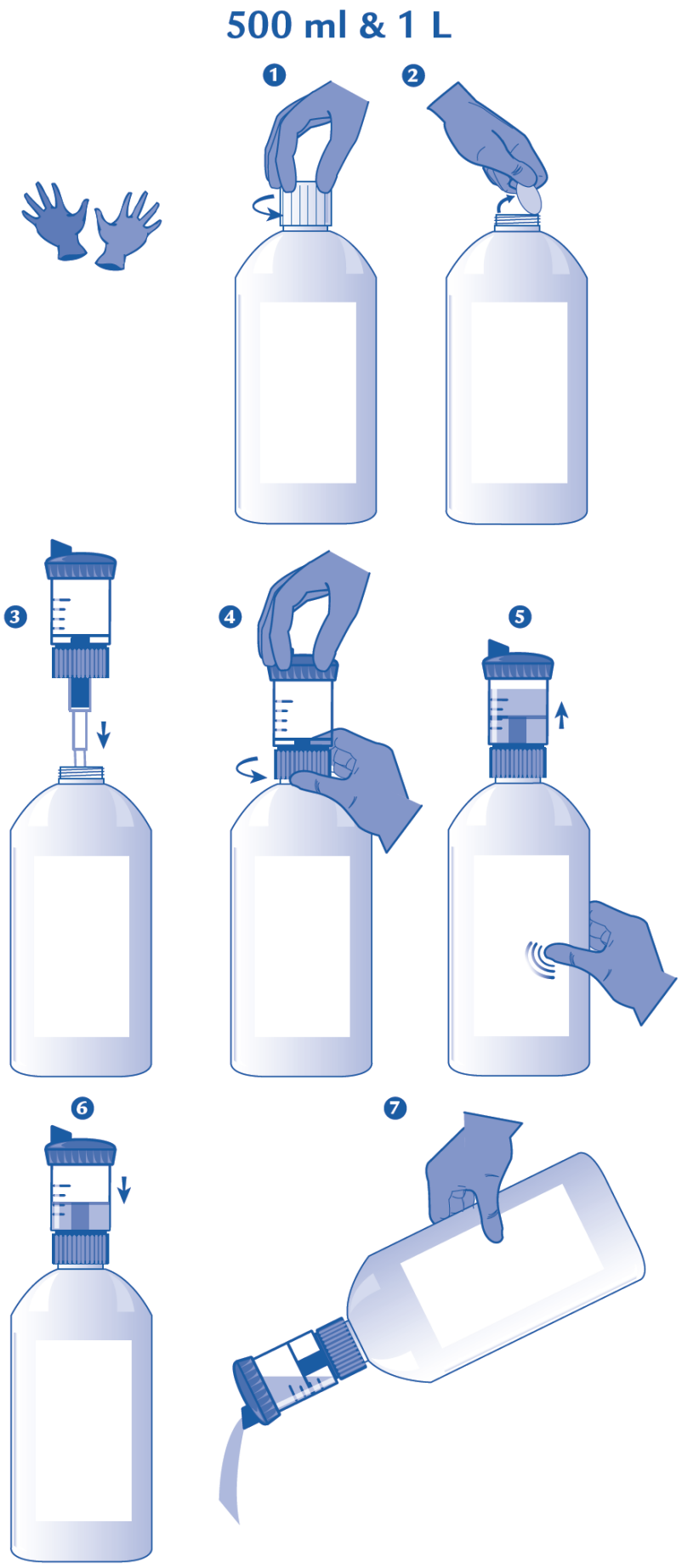
For external use. Pour-on application.

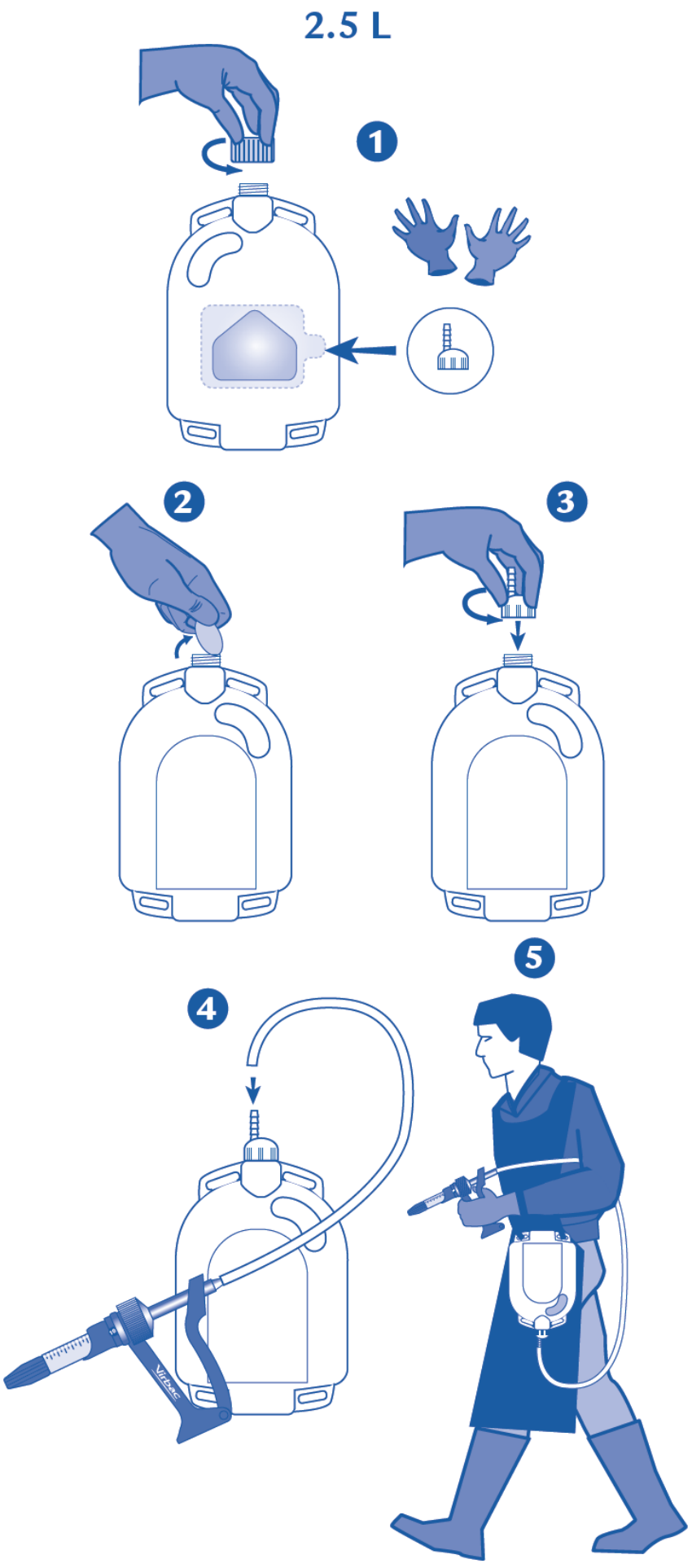
Dose:
Cattle: 100 mg of deltamethrin per animal corresponding to 10 ml of veterinary medicinal product.
Sheep: 50 mg of deltamethrin per animal corresponding to 5 ml of veterinary medicinal product
Lambs (under 10 kg bodyweight or 1 month of age): 25 mg of deltamethrin per animal corresponding to 2.5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

Administration:
The veterinary medicinal product should be applied using an appropriate device :
- for the 0.5 litre and 1 litre bottles, the veterinary medicinal 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.

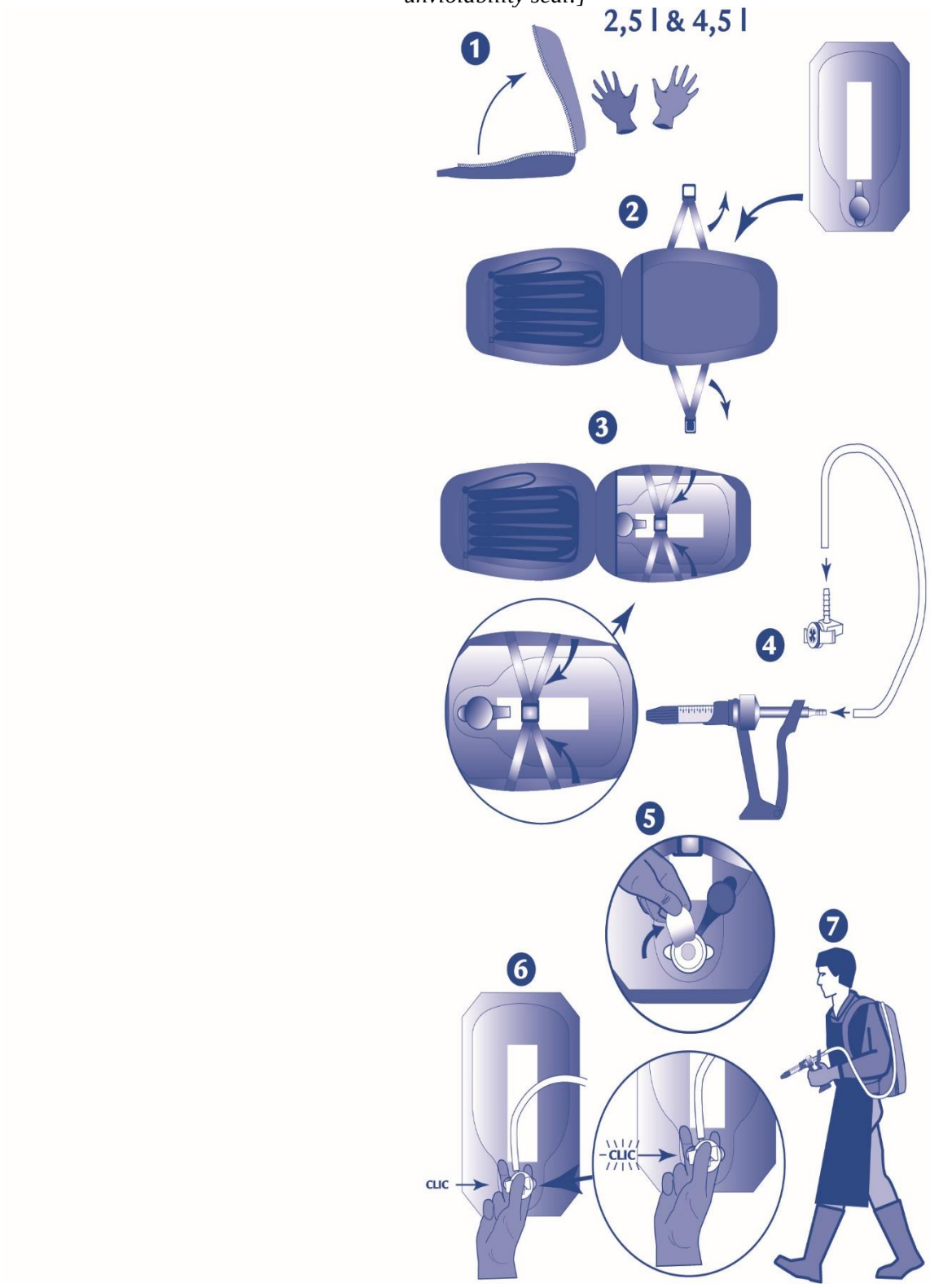
An appropriate applicator should comply with the following specifications :
- it should deliver doses of 2.5 ml, 5 ml and 10 ml.

- it should be supplied with a flexible hose of internal diameter between 10 mm and 14 mm.


500 ml & 1 L
1
2
3
4
5
6
7


2.5 L
1
2
3
4
5

[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.

Application site :
Apply the veterinary medicinal 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 veterinary medicinal 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.

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

3.12 Withdrawal periods

Cattle:
Meat and offal: 17 days
Milk: zero hours

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

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QP53AC11

4.2 Pharmacodynamics

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.

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. 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.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

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

5.2 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

5.3. Special precautions for storage

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

5.4 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.

5.5 Special precautions for the disposal of unused veterinary medicinal products 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 this may be dangerous for fish and other aquatic organisms.

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

VIRBAC

7. MARKETING AUTHORISATION NUMBER(S)

8. DATE OF FIRST AUTHORISATION

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

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).

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

BOTTLES; FLEXIBLE POUCHES

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Deltanil 10 mg/ml pour-on solution

2. STATEMENT OF ACTIVE SUBSTANCES

Deltamethrin 10 mg/ml

3. PACKAGE SIZE

500 ml bottle
1 l bottle
2.5 l bottle
2.5 l flexible pouch (Flexibag)
4.5 l flexible pouch (Flexibag)

4. TARGET SPECIES

Cattle and sheep.

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Pour-on use.

7. WITHDRAWAL PERIODS

Withdrawal period:
Cattle:
Meat and offal: 17 days
Milk: zero hours
Sheep:
Meat and offal: 35 days
Milk: zero hours

8. EXPIRY DATE

Exp. {mm/yyyy}

For bottles only: Once opened use within1 year.
For pouches only: Once opened use within 2 years.

9. SPECIAL STORAGE PRECAUTIONS

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

10. THE WORDS "READ THE PACKAGE LEAFLET BEFORE USE"

Read the package leaflet before use.

11. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

12. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

VIRBAC

14. MARKETING AUTHORISATION NUMBERS

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

500 ML AND 1 L BOTTLES; FLEXIBLE POUCHES

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Deltanil 10 mg/ml pour-on solution

2. STATEMENT OF ACTIVE SUBSTANCES

Deltamethrin 10 mg/ml

3. TARGET SPECIES

Cattle and sheep.

4. ROUTES OF ADMINISTRATION

Pour-on use.

Read the package leaflet before use.

5. WITHDRAWAL PERIODS

Withdrawal period:
Cattle:
Meat and offal: 17 days
Milk: zero hours
Sheep:
Meat and offal: 35 days
Milk: zero hours

6. EXPIRY DATE

Exp. {mm/yyyy}
For bottles only: Once opened, use within 1 year
For pouches only: Once opened, use within 2 years
Once opened use by…

7. SPECIAL STORAGE PRECAUTIONS

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

8. NAME OF THE MARKETING AUTHORISATION HOLDER

VIRBAC

9. BATCH NUMBER

Lot {number}

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Deltanil 10 mg/ml pour-on solution for cattle and sheep

2. Composition

Each ml contains:
Active substance:
Deltamethrin 10 mg

Slightly yellowish clear oily solution.

3. Target species

Cattle and sheep.

4. Indications for use

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 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 to any of the excipients.
Do not use in animals with extensive lesions of the skin.
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.

6. Special warnings

Special warnings:

To avoid resistance, the veterinary medicinal 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 veterinary medicinal product should ideally be based on results of susceptibility testing. Please, ask your veterinarian for further information.
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. The strategic use of the veterinary medicinal 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 veterinary medicinal product, or lack of calibration of the dosing device.

Special precautions for safe use in the target species:

Do not apply on or near the animal's eyes and mucous membranes.
The veterinary medicinal 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 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 veterinary medicinal product or one of its components should avoid contact with the veterinary medicinal product.
Personal protective equipment consisting of protective clothing including 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 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 immediately 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.

Pregnancy and lactation:

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:

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.

Major incompatibilities:

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

7. Adverse events

Cattle / Sheep:

Very rare (< 1 animal / 10,000 animals treated, including isolated reports):
Application site reactions[1] (e.g. application site squamosis, application site pruritus)

[1] Observed in cattle during the 48 hours after treatment.

Reporting adverse events is important. It allows continuous safety monitoring of a product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder or the local representative of the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system: {national system details}

8. Dosage for each species, routes and method of administration

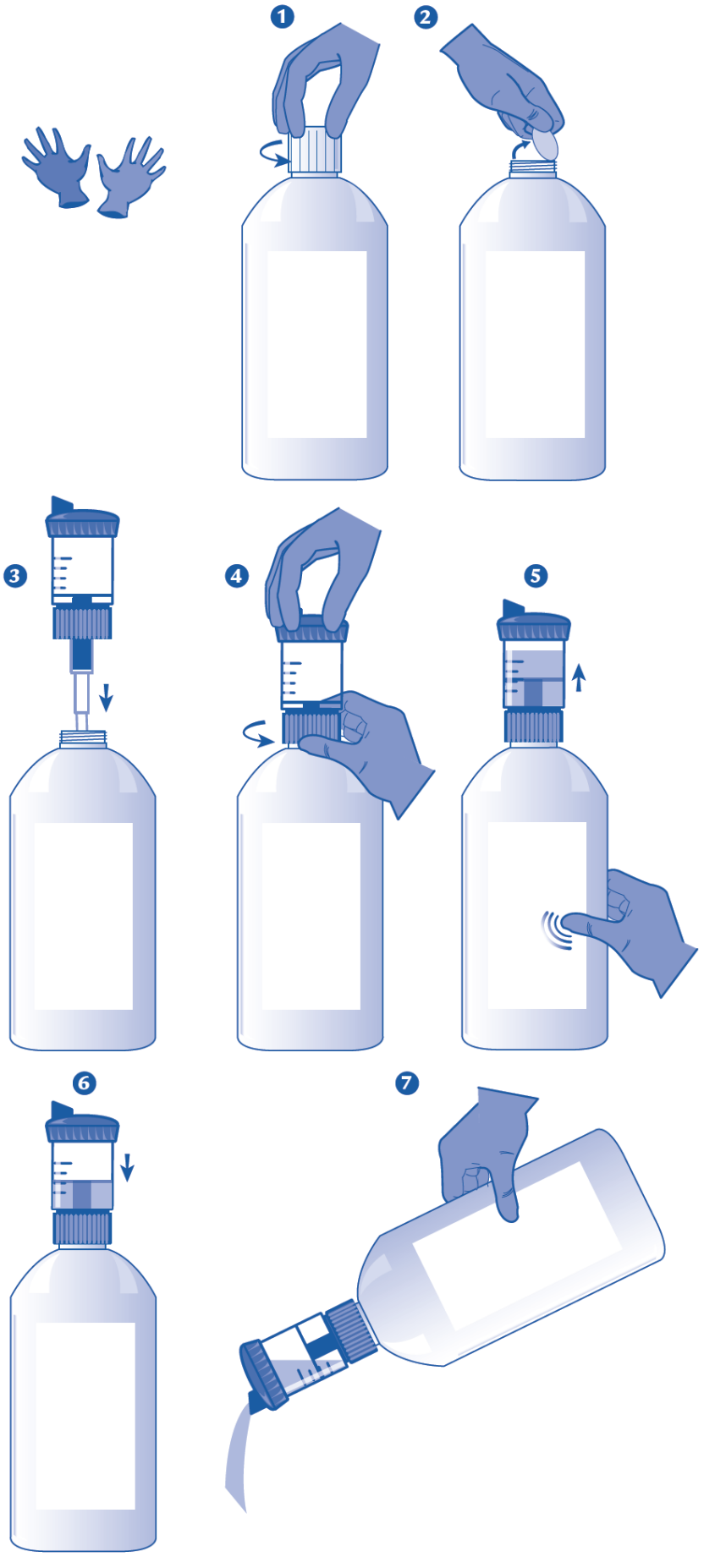
For external use. Pour-on application.

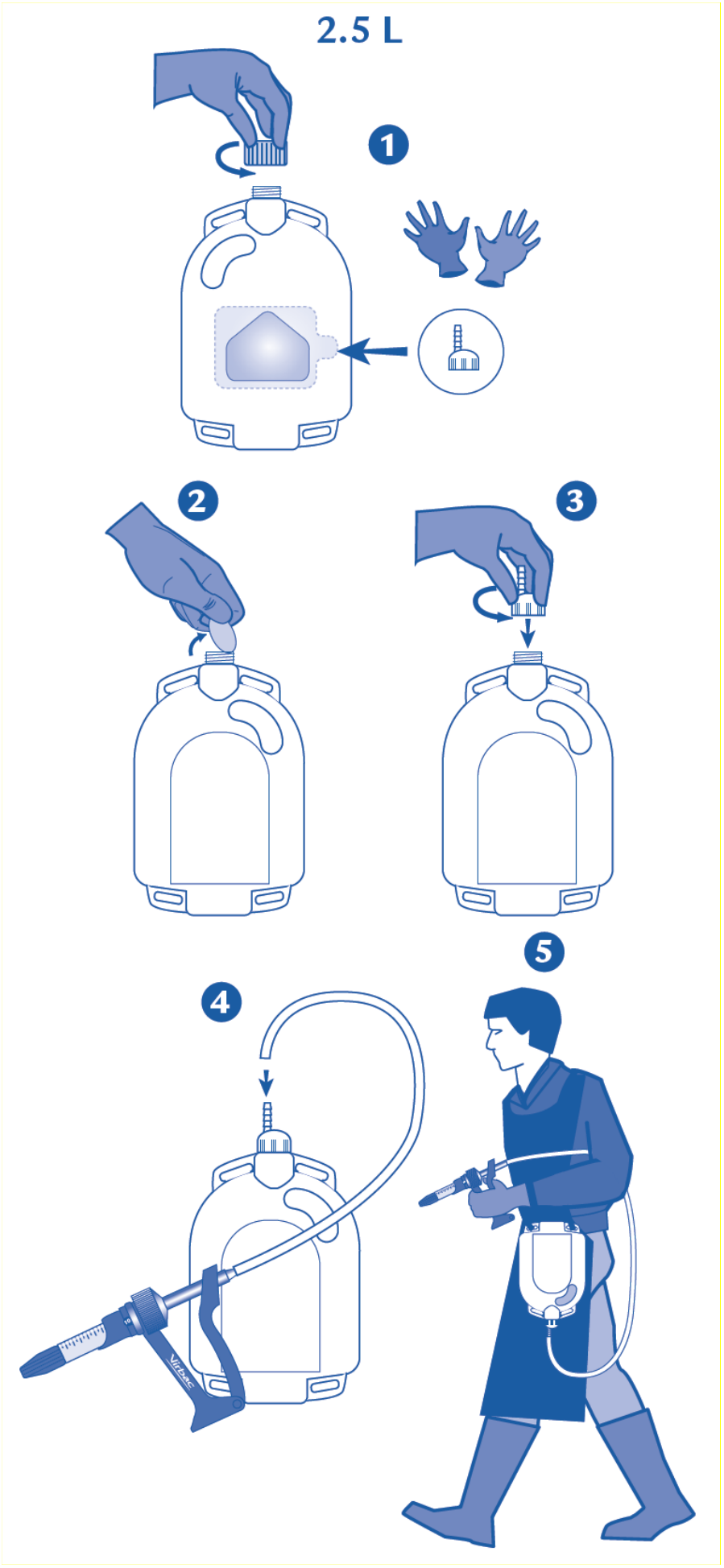
Dose:
Cattle: 100 mg of deltamethrin per animal corresponding to 10 ml of veterinary medicinal product.
Sheep: 50 mg of deltamethrin per animal corresponding to 5 ml of veterinary medicinal product.
Lambs (under 10 kg bodyweight or 1 month of age): 25 mg of deltamethrin per animal corresponding to 2.5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

Administration:
When using a multi-dose container, the veterinary medicinal product should be applied using an appropriate device :
- for the 0.5 litre and 1 litre bottles, the veterinary medicinal 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.

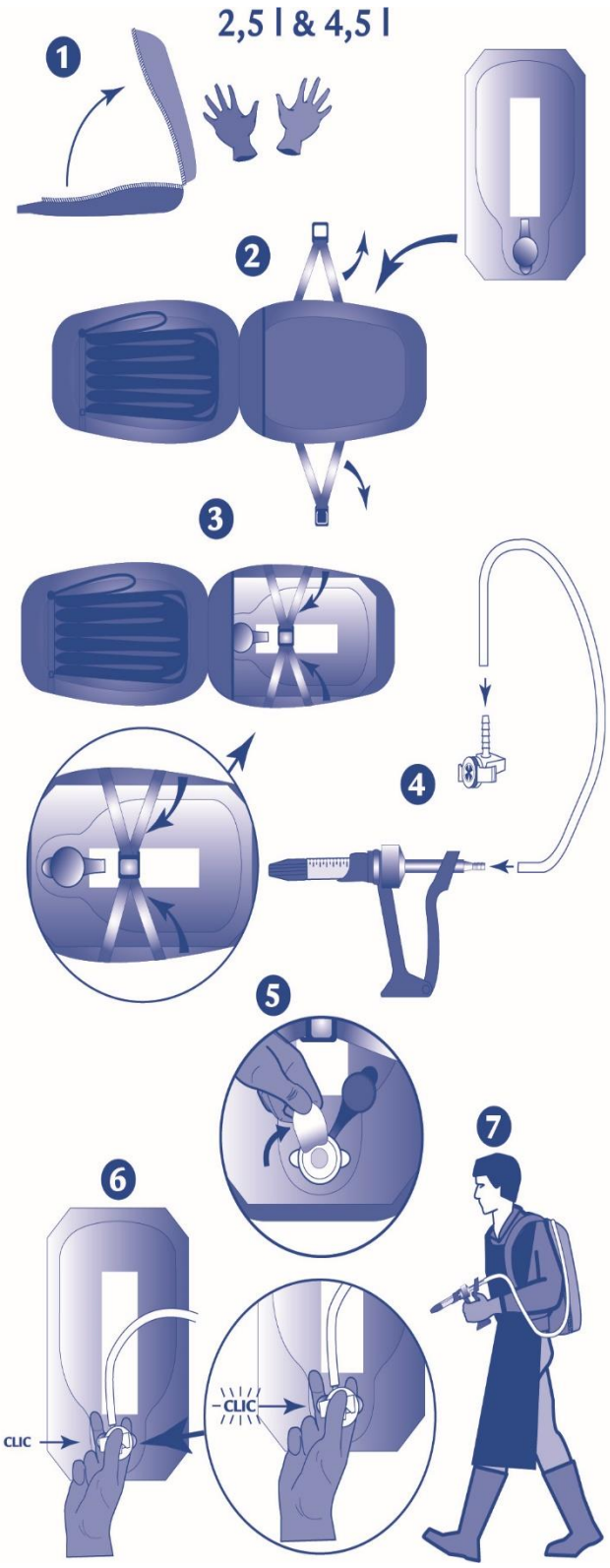
An appropriate applicator should comply with the following specifications :
- it should deliver doses of 2.5 ml, 5 ml and 10 ml.
- it should be supplied with a flexible hose of internal diameter between 10 mm and 14 mm.

500 ml & 1 L




2.5 L
1
2
3
4
5

[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 veterinary medicinal 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 veterinary medicinal 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 periods

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 this veterinary medicinal product after the expiry date which is 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

12. Special precautions for disposal

Medicines should not be disposed of via wastewater or household waste.

This veterinary medicinal product should not enter water courses as this may be dangerous for fish and other aquatic organisms.

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 applicable national collection systems. These measures should help to protect the environment.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

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.

15. Date on which the package leaflet was last revised

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

16. Contact details

Marketing authorisation holder and manufacturer responsible for batch release and contact details to report suspected adverse reactions:

VIRBAC
1ère avenue 2065m LID
06516 Carros
France

Local representatives and contact details to report suspected adverse reactions:

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

17. 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.