PARTICULARS TO APPEAR ON THE OUTER PACKAGE {CARTON BOX for 500 ml and 1L package sizes}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE {HDPE bottle for 2.5 L package size as there is no outer package}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each ml contains:

Active substance:
Deltamethrin 10 mg

Excipients: Triglycerides medium-chain (939.5 mg)

3. PACKAGE SIZE

500 ml
1 L
2.5 L

4. TARGET SPECIES

Cattle and sheep

5. 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.

For further details, please refer to the package leaflet.

6. ROUTES OF ADMINISTRATION

Pour-on use.

Read the package leaflet before use.

Dosing: Cattle: 10ml; Sheep: 5ml; Lambs (under 10kg weight or 1 month of age): 2.5ml

7. WITHDRAWAL PERIODS

Withdrawal periods:

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

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

8. EXPIRY DATE

EXP {mm/yyyy}

Once opened, use within 1 year.

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

Vm 05653/5048

15. BATCH NUMBER

Lot {number}

16. SPECIAL WARNING(S), IF NECESSARY

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

Disposal: read package leaflet.

18. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE

POM-VPS ('Veterinary medicinal product subject to prescription')

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE {HDPE BOTTLE for 500 ml and 1 L}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each ml contains:

Active substance:
Deltamethrin 10 mg

Excipients: Triglycerides medium-chain (939.5 mg)

3. TARGET SPECIES

Cattle and sheep

4. ROUTES OF ADMINISTRATION

Pour-on use.

5. WITHDRAWAL PERIODS

Withdrawal periods:

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

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

6. EXPIRY DATE

EXP {mm/yyyy}

Once opened, use within 1 year.

7. SPECIAL STORAGE PRECAUTIONS

Keep the bottle in the outer carton.

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}

10. SPECIAL WARNING(S), IF NECESSARY

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

Disposal: read package leaflet.

12. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE

For animal treatment only.

POM-VPS (‘Veterinary medicinal product subject to prescription’)

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. COMPOSITION

Each ml contains:

Active substance:
Deltamethrin 10 mg

Excipients: Triglycerides medium-chain (939.5 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 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*.

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. SPECIAL WARNING(S)

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. 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 recognised 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 safe use in the target species:
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:
Deltamethrin can cause hypersensitivity (allergic) reactions. People with known hypersensitivity to deltamethrin should avoid contact with the 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.

Special precautions for 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.
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.

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 and sheep:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Application site skin squamosis[1], Application site pruritus[1]

[1]Within 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 its local representative using the contact details at the end of this leaflet, or via your national reporting system.

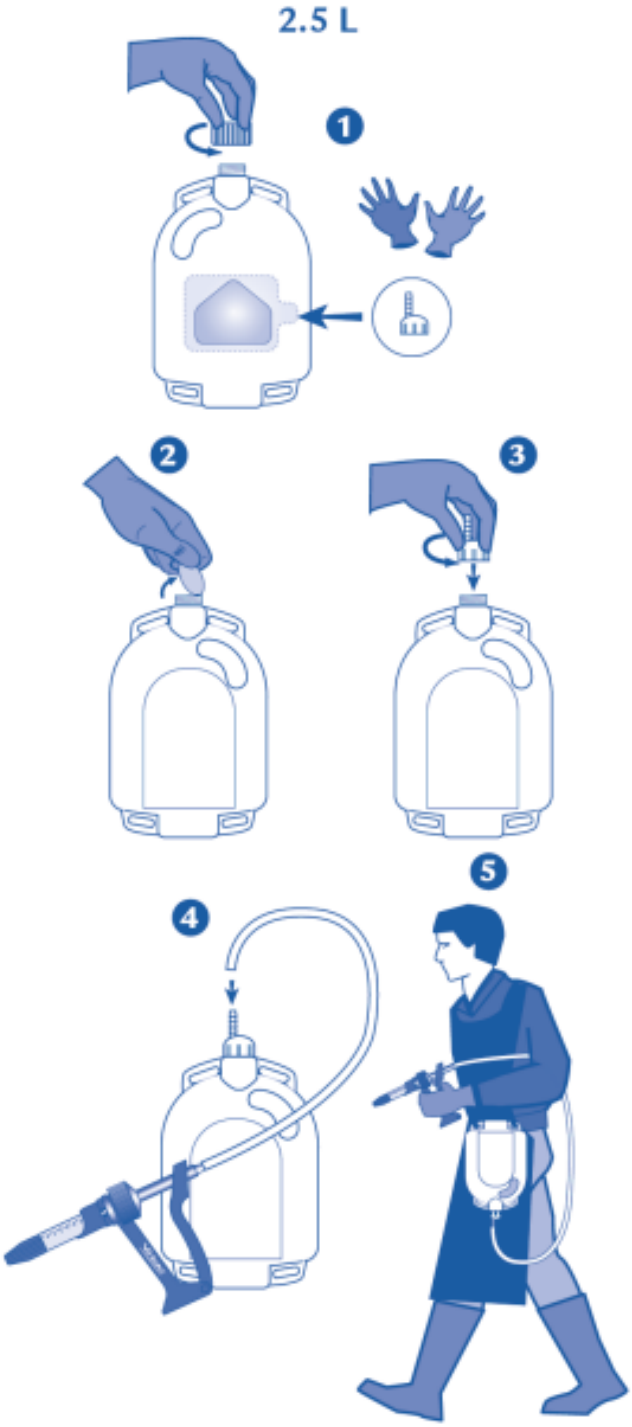
8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

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, it is recommended to use an appropriate dosing gun.

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

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(S)

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

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

11. SPECIAL STORAGE PRECAUTIONS

Store in tightly closed original container away from food, drink and animal feeding stuffs.
Shelf-life after first opening the immediate packaging: 1 year

Do not use this veterinary medicinal product after the expiry date which is stated on the carton/bottle after EXP. The expiry date refers to the last day of that month.

Keep out of the sight and reach of children.

12. SPECIAL PRECAUTIONS FOR DISPOSAL

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.

13. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

14. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

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.

Not all pack sizes may be marketed.

Vm 05653/5048

15. PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

16. CONTACT DETAILS

Marketing authorisation holder and manufacturer responsible for batch release:

VIRBAC
1ère avenue 2065m LID
06516 Carros
France

Local representative and contact details to report suspected adverse reactions:
Downland Marketing Ltd
Warwick Mill Business Centre
Warwick Bridge
Carlisle, CA4 8RR, UK
01228 564498

17. OTHER INFORMATION

POM-VPS ('Veterinary medicinal product subject to prescription')

For animal treatment only.

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 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.

Gavin Hall
Approved: 11 August 2025