

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Deltanil 100 mg Spot-on Solution for cattle
Deltamethrin

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each 10 ml tube contains :
Deltamethrin 100 mg

3. PHARMACEUTICAL FORM

Spot-on Solution

4. PACKAGE SIZE



5. TARGET SPECIES

Cattle

6. INDICATION(S)

For the treatment and prevention of infestations by lice and flies on cattle.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Spot-on use.

Read package leaflet before use.

8. WITHDRAWAL PERIOD

Meat and offal: 17 days

Milk: zero hours

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}

11. SPECIAL STORAGE CONDITIONS

Read the package leaflet before use.

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 REACH AND SIGHT OF CHILDREN”

Keep out of the reach and sight of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

VIRBAC

1ère avenue – 2065m – L.I.D.

06516 Carros

FRANCE

16. MARKETING AUTHORISATION NUMBER(S)

17. MANUFACTURER’S BATCH NUMBER

Lot {number}

**MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING
UNITS
10-ML TUBES**

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Deltanil 100 mg Spot-on Solution for cattle



Deltamethrin

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Each 10 ml tube contains
Deltamethrin 100 mg

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

10 ml

4. ROUTE(S) OF ADMINISTRATION

Cutaneous route.

5. WITHDRAWAL PERIOD

Meat and offal: 17 days
Milk: zero hours

6. BATCH NUMBER

<Lot> {number}

7. EXPIRY DATE

<EXP {month/year}>

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

Ad us. vet.

PACKAGE LEAFLET FOR Deltanil 100 mg Spot-on Solution for cattle

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:

VIRBAC
1ère avenue – 2065m – L.I.D.
06516 Carros
FRANCE

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Deltanil 100 mg Spot-on Solution for cattle

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

Each 10 ml tube contains:

Active substance:

Deltamethrin 100 mg

4. INDICATION(S)

As a topical application for the treatment and prevention of infestations by lice and flies 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*.

5. CONTRAINDICATIONS

Do not use on convalescent or sick animals.

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

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

Squamosis and pruritus have been seen in some cattle during the 48 hours after treatment.

If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinarian.

7. TARGET SPECIES

Cattle.

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

For external use.

Dose: 100 mg of deltamethrin per cattle corresponding to the entire content of the 10 ml tube.

Administration:

Apply the entire contents of the 10 mL tube

9. ADVICE ON CORRECT ADMINISTRATION

Application site :

Apply the product on one spot on the mid-line of the back at the shoulders.

Lice: 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: Where horn-flies predominate, good treatment and prevention of infestations can be expected for 4 - 8 weeks.

10. WITHDRAWAL PERIOD

Meat and offal: 17 days

Milk: zero hours

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the reach and sight 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 tube.

12. SPECIAL WARNING(S)

Special warnings

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

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.

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.

Special precautions for use

Special precautions for use in animals

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, consult your doctor and show this label.

Other precautions

Deltamethrin is toxic to dung insects. The risk to dung fauna can be reduced by avoiding too frequent and repeated use of deltamethrin (and other synthetic pyrethroids) in cattle, e.g. by using a single treatment per year on the same pasture.

Use during pregnancy, lactation or lay

Laboratory 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 pregnant cows during pregnancy and lactation only accordingly to the 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), if necessary

Some adverse effects have been seen following overdose. These include paraesthesia and irritation and have been shown to be mild, transient and resolve without treatment.

Incompatibilities

None known.

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

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.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

Detailed information on this product is available on the website of the European Medicines Agency (EMA) <http://www.emea.europa.eu/>.

15. OTHER INFORMATION

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.

Pharmacokinetic particulars

After dermal application, deltamethrin is slightly absorbed through skin of cattle.

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 toxic to aquatic organisms and honey bees and may accumulate in sediment.

10 ml tube, carton box of 10 tubes.

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