

**MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS**

Front label, 2.5 Litre

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Deltamole 7.5 mg/ml pour-on suspension for cattle  
Deltamethrin

**2. QUANTITY OF THE ACTIVE SUBSTANCE(S)**

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

2.5 Litre

**4. ROUTE(S) OF ADMINISTRATION**

Pour-on suspension.

**5. WITHDRAWAL PERIOD(S)**

Read the package leaflet before use.

**6. BATCH NUMBER**

BN:

**7. EXPIRY DATE**

EXP: {month/year}

**8. THE WORDS "FOR ANIMAL TREATMENT ONLY"**

For animal treatment only.

Long acting, ready-to-use topical ectoparasiticide.

For the control of biting and nuisance flies, biting and sucking lice of cattle.

**PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE**

{**CONCERTINA LABEL<sup>1</sup>** – Base Label and Top Label}

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Deltamole 7.5 mg/ml pour-on suspension for cattle  
Deltamethrin

**2. STATEMENT OF ACTIVE SUBSTANCES**

Each ml of Deltamole pour-on suspension contains 7.5 mg of deltamethrin.

**3. PHARMACEUTICAL FORM**

Pour-on suspension.

**4. PACKAGE SIZE**

2.5 Litre

**5. TARGET SPECIES**

Cattle.

**6. INDICATION(S)**

Long acting, ready-to-use topical ectoparasiticide.  
For the control of biting and nuisance flies, biting and sucking lice of cattle.  
**Read the package leaflet before use.**

**7. METHOD AND ROUTE(S) OF ADMINISTRATION**

**For external use only.**

**Read the package leaflet before use.**

**8. WITHDRAWAL PERIOD(S)**

**Withdrawal period:** Meat and offal: 20 days  
Milk: Zero hours

**9. SPECIAL WARNING(S), IF NECESSARY**

**Read the package leaflet before use.**

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<sup>1</sup> For concertina labels, the immediate label template heading requirements must begin and end the proposal. The leaflet requirements should go in-between. The immediate label must be stuck to the container and be replicated on the outer facing part of the concertina label.

**10. EXPIRY DATE**

EXP End of:

**11. SPECIAL STORAGE CONDITIONS**

**Storage:**

Protect from direct sunlight.

Keep away from food, drink and animal feeding stuffs.

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

Read the package leaflet before use.

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

POM-VPS

To be supplied only on veterinary prescription.

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**

MSD Animal Health UK Ltd.  
Walton Manor, Walton  
Milton Keynes  
MK7 7AJ

**16. MARKETING AUTHORISATION NUMBER (S)**

Vm 01708/4609

**17. MANUFACTURER'S BATCH NUMBER**

BN:

**PACKAGE LEAFLET:**  
**Deltamole 7.5 mg/ml pour-on suspension 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:

MSD Animal Health UK Ltd.  
Walton Manor, Walton  
Milton Keynes  
Buckinghamshire  
MK7 7AJ

Manufacturer responsible for batch release:

Intervet Productions  
Rue de Lyons  
27460 Igoville  
France

**2. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Deltamole 7.5 mg/ml pour-on suspension for cattle  
Deltamethrin

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

Each ml of Deltamole pour-on suspension contains 7.5 mg of deltamethrin in an aqueous suspension.  
Off-white homogenous suspension.

**4. INDICATION(S)**

Long-acting, ready-to-use topical ectoparasiticide.

Control of biting and nuisance flies of cattle, including *Haematobia irritans*, *Hippobosca equina*, *Stomoxys calcitrans*, *Musca autumnalis* and *Musca domestica*.

Control of biting and sucking lice of cattle, including *Damalinia bovis*, *Haematopinus eurysternus*, and *Linognathus vituli*.

**5. CONTRAINDICATIONS**

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

Do not use on animals with major skin lesions.

**6. ADVERSE REACTIONS**

Application site reactions including erythema and pruritus, hyperactivity, anxiety and

hypersensitivity have been reported in very rare cases in post-marketing experience.

The frequency of adverse reactions is defined using the following convention:

- very common (more than 1 in 10 animals displaying adverse reaction(s) during the course of one treatment)
- common (more than 1 but less than 10 animals in 100 animals)
- uncommon (more than 1 but less than 10 animals in 1,000 animals)
- rare (more than 1 but less than 10 animals in 10,000 animals)
- very rare (less than 1 animal in 10,000 animals, including isolated reports).

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 inform your veterinary surgeon.

## 7. TARGET SPECIES

Cattle.

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

For external use only.

The required volume of product should be applied along the midline of the animal's back, from the head to the tail, at the following recommended dose rates:

Indications	Dose rate
<b>Flies:</b> Control of biting and nuisance flies	up to 100 kg : 10 ml 100 – 300 kg : 20 ml over 300 kg : 30 ml
<b>Lice:</b> Control of biting and sucking lice	10 ml per animal irrespective of bodyweight.

**Flies:** a single application provides protection against flies for 8-10 weeks depending on the infestation degree, fly species and weather conditions.

Treatment should be repeated within 8-10 weeks depending on the weather and the fly species.

**Lice:** a single application provides protection against lice for 8-10 weeks. All in contact animals must be treated at the same time. A single application is sufficient against lice.

## 9. ADVICE ON CORRECT ADMINISTRATION

Refer to Section 8.

## 10. WITHDRAWAL PERIOD(S)

**Withdrawal period:** Meat and offal: 20 days  
Milk: Zero hours

## 11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

Protect from direct sunlight.

Keep away from food, drink and animal feeding stuffs.

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

## 12. SPECIAL WARNING(S)

### Special warnings for each target species:

Cases of resistance to deltamethrin have been reported in stinging and nuisance flies in cattle. 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. Therefore, the use of this product should be based on local (regional and farm) 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.

If clinical signs do not resolve following treatment, the diagnosis should be revised.

### Special precautions for use in animals:

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

Care should be taken to prevent the animal licking 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 already be affected by infestation.

### Special precautions to be taken by the person administering the veterinary medicinal product to animals:

People with known hypersensitivity to deltamethrin should avoid contact with the veterinary medicinal product.

Personal protective equipment consisting of waterproof apron and boots and impervious gloves should be worn when either applying or handling the veterinary medicinal product or 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 and seek medical advice.

Do not eat, drink or smoke while handling the product.

This product contains deltamethrin, which may produce tingling, itching and blotchy

redness on exposed skin. Irritation, sensitisation and adverse effects on the neuronal system might occur. If you feel unwell after working with this product, seek medical advice immediately and show the package leaflet or the label to the physician.

Information for doctors: Advice on clinical management is available from the National Poisons Information Service.

Pregnancy and lactation:

No restrictions apply for use during pregnancy and lactation.

Interaction with other medicinal products and other forms of interaction:

Some organo-phosphorous insecticides can reduce metabolism rate and thus enhance deltamethrin toxicity. Therefore, avoid the use of such organo-phosphorous insecticides (consult the supplier).

Overdose (symptoms, emergency procedures, antidotes):

Overdose of twice the level of recommended treatments does not induce any adverse effects.

Other precautions:

Deltamethrin is very toxic to dung fauna and aquatic organisms. 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 only a single treatment per season on the same pasture.

**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 empty containers. 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**

March 2023

**15. OTHER INFORMATION**

For animal treatment only.

**Environmental properties**

Deltamethrin is very toxic to dung fauna, aquatic organisms and honey bees. It is persistent in soils and may accumulate in sediments.

Deltamethrin has the potential to adversely affect non-target organisms, both in water and in dung. Following treatment, excretion of deltamethrin levels potentially toxic to dung fauna 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 which may impact on the dung degradation.

2.5 L portable polyethylene bottle closed with a polypropylene stopper fitted with a

heat-sealable aluminium-polyethylene seal (for use with an applicator gun).

POM-VPS

To be supplied only on veterinary prescription.

Vm 01708/4609

**Distributor**

Mole Valley Farmers Ltd.  
Station Road  
South Molton  
Devon  
EX36 3BH

Approved 31 March 2023

A handwritten signature in black ink, appearing to read "A. Hunter.", positioned below the approval date.