

PARTICULARS TO APPEAR ON THE OUTER PACKAGE
{CONCERTINA LABEL¹ – 2.5 Litre (Base Label and Top Label)}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Deltamole 7.5 mg/ml pour-on suspension for cattle

2. STATEMENT OF ACTIVE SUBSTANCES

Deltamethrin 7.50 mg/ml

3. PACKAGE SIZE

2.5 Litres

4. TARGET SPECIES

Cattle.

5. INDICATIONS

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

6. ROUTES OF ADMINISTRATION

Pour-on use.
For external use only.

7. WITHDRAWAL PERIODS

Withdrawal periods: Meat and offal: 20 days.
Milk: Zero hours.

8. EXPIRY DATE

Exp. {mm/yyyy}

9. SPECIAL STORAGE PRECAUTIONS

Protect from direct sunlight.
Keep 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

Intervet International B.V.

14. MARKETING AUTHORISATION NUMBERS

Vm 06376/4101

15. BATCH NUMBER

Lot {number}

¹ 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.

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

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Deltamethrin 7.50 mg/ml

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

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp: {mm/yyyy}

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Deltamole 7.5 mg/ml pour-on suspension for cattle

2. Composition

Each ml contains:

Active substance:

Deltamethrin 7.50 mg

Excipients:

Formaldehyde solution (35 %) 0.19 mg

Off-white homogenous suspension.

3. Target species

Cattle.

4. Indications for use

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*, *Haematpoinus 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. Special warnings

Special warnings:

Cases of resistance to deltamethrin have been reported in stinging and nuisance flies in cattle. 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. Therefore, the use of this veterinary medicinal 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 veterinary medicinal 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 safe use in the target species:

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

Care should be taken to prevent the animal licking 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 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 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 and seek medical advice.

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

This veterinary medicinal 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 veterinary medicinal product, seek medical advice immediately and show the package leaflet or the label to the physician.

To the physician: Advice on clinical management is available from the National Poisons Information Service.

Special precautions for the protection of the environment:

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.

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:

Twice the recommended dose in cattle does not induce any clinical adverse effects.

Major incompatibilities:

None known.

7. Adverse events

Cattle:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Application site erythema, Application site pruritus; Hyperactivity, Anxiety; Hypersensitivity reaction.
---	---

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 at:

Website: <https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine>

e-mail: adverse.events@vmd.gov.uk

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

Pour-on use.

For external use only.

The required volume of the veterinary medicinal 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
Flies: Control of biting and nuisance flies	up to 100 kg: 10 ml 100 – 300 kg: 20 ml over 300 kg: 30 ml

Lice: 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

To ensure a correct dosage, body weight should be determined as accurately as possible.

10. Withdrawal periods

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 on the label after Exp. The expiry date refers to the last day of that month.

12. Special precautions for disposal

Medicines should not be disposed of via wastewater.

This veterinary medicinal product should not enter water courses as Deltamethrin may be dangerous for fish and other aquatic organisms. Do not contaminate ponds, waterways or ditches with this veterinary medicinal product or used containers.

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

Vm 06376/4101

2.5 Litre portable polyethylene bottle closed with a polypropylene stopper fitted with a heat-sealable aluminium-polyethylene seal (for use with an applicator gun).

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:

Intervet International B.V.
Wim de Körverstraat 35
5831 AN Boxmeer
The Netherlands

Manufacturer responsible for batch release:

Intervet Productions S.A.
Rue de Lyons
27460 Igoville
France

Local representative and contact details to report suspected adverse reactions:

MSD Animal Health UK Limited
Walton Manor, Walton
Milton Keynes
MK7 7AJ, United Kingdom
Tel.: +44 (0)1908 685685

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

17. Other information

POM-VPS

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.

Gavin Hall

Approved 22 February 2026