

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Deltamole 7.5 mg/ml pour-on suspension for cattle

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance:

Deltamethrin 7.50 mg

Excipients:

Qualitative composition of excipients and other constituents	Quantitative composition if that information is essential for proper administration of the veterinary medicinal product
Formaldehyde solution (35 %)	0.19 mg
Sodium laurilsulfate	
Silica, precipitated	
Xanthan gum	
Citric acid monohydrate	
Propylene glycol	
Water, purified	
Rhodorsil antifoam 416	
Rhodorsil antifoam 426R	
Dispersing agent SI	

Off-white homogenous suspension.

3. CLINICAL INFORMATION

3.1 Target species

Cattle.

3.2 Indications for use for each target species

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*.

3.3 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.

3.4 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 product, or lack of calibration of the dosing device.

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

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.

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.

3.6 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 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

Pregnancy and lactation:

No restrictions apply for use during pregnancy and lactation.

3.8 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).

3.9 Administration routes and dosage

Pour-on use.

For external use only.

Pour the veterinary medicinal product along the backline of the animals, 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 to 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 to 10 weeks. All in contact animals must be treated at the same time. A single application is sufficient against lice.

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

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

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

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

Not applicable.

3.12 Withdrawal periods

Meat and offal: 20 days.

Milk: Zero hours.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QP53AC11

4.2 Pharmacodynamics

The veterinary medicinal product is an ectoparasiticide whose active ingredient deltamethrin belongs to the synthetic pyrethroids class. Its mode of action affects the neurotransmission in the target parasite.

4.3 Pharmacokinetics

After dermal application, deltamethrin is slightly absorbed through skin of cattle and sheep and remains available to the target ectoparasite. The main route of excretion of the absorbed amount in the target animal is the faeces. In terms of residues, fat is the target issue.

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.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

None known.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years.

5.3 Special precautions for storage

Protect from direct sunlight. Keep away from food, drink and animal feeding stuffs.

5.4 Nature and composition of immediate packaging

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).

5.5 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

Medicines should not be disposed of via wastewater.

The 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 the product or empty 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 national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Intervet International B.V.

7. MARKETING AUTHORISATION NUMBER

Vm 06376/4101

8. DATE OF FIRST AUTHORISATION

17 December 2014

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

November 2025

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCT

Veterinary medicinal product subject to prescription.

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

Gavin Hall
Approved: 17 December 2025