

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Butox 7.5 mg/ml Pour On Suspension

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 35 % solution	0.19 mg
Propylene Glycol	160.0 mg
Sodium Laurylsulfate	
Precipitated silica	
Xanthan Gum	
Citric Acid Monohydrate	
Purified Water	
Antifoam (Rhodorsil 416)	
Antifoam (Rhodorsil 426R)	
Dispersing agent SI	

* A mixture of a condensation product of arylsulfonate and aldehyde, and alkylether sulfate and silicic acid

Off-white to pale brown pour-on suspension.

3. CLINICAL INFORMATION

3.1 Target species

Cattle and sheep.

3.2 Indications for use for each target species

Prevention and treatment of cattle flies.
Prevention and treatment of cattle and sheep lice.
Prevention and treatment of sheep keds.

3.3 Contraindications

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

3.4 Special warnings

Cases of resistance to deltamethrin have been reported in parasites of cattle and sheep. Use of this product should be based on local (regional, farm) epidemiological information about parasite susceptibility to deltamethrin.

3.5 Special precautions for use

Special precautions for safe use in the target species:

None.

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

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

Wash hands and exposed skin before meals and after work.

Avoid contact with skin, eyes and mucous membranes, and oral uptake. Wear impervious gloves.

Change heavily contaminated clothes and wash before re-use.

In case of skin contact, wash the exposed parts thoroughly with water and soap.

In case of eye or mucous membrane contact, immediately rinse thoroughly with water.

People with known hypersensitivity to the veterinary medicinal product or one of its components should avoid contact with the veterinary medicinal product. If you feel unwell after the use of the veterinary medicinal product, seek medical advice immediately and show the package leaflet or the label to the physician.

Special precautions for the protection of the environment:

Deltamethrin must not enter surface water as it is toxic to fish and other aquatic organisms.

3.6 Adverse events

Cattle and Sheep:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Hypersensitivity reaction Skin irritation Restlessness ¹
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¹Including tail flicking and head shaking behaviour.

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 the national competent authority via the national reporting system. See the package carton for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy and lactation:

Can be used 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, it is not advisable to use in association with organo-phosphate insecticides.

3.9 Administration routes and dosage

Pour-on use.

Apply the recommended dose by pouring it along the animal's spine from the base of the head to the tail. For sheep, it is recommended that the fleece is parted during administration.

<i>Indications</i>	<i>Dose Rate</i>
Flies Prevention and treatment of flies on calves and other cattle	Cattle - Up to 100 kg: 10 ml - 100 kg to 300 kg: 20 ml - Over 300 kg: 30 ml
Lice Prevention and treatment of biting and sucking lice on calves, adult cattle and sheep	Cattle, sheep 10 ml per animal irrespective of weight
Keds Prevention and treatment of sheep keds	Sheep 10 ml per animal

Lice:

One single application is generally enough for 8-10 weeks protection, but in cases of heavy infestation it may be necessary to repeat the treatment after 4-6 weeks. All in contact animals must be treated at the same time.

Flies:

One single application provides protection against flies for 6-10 weeks depending on the degree of infestation, fly species and weather conditions.

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

Overdose of twice the recommended treatment dose does not induce any 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: Cattle: 18 days.
Sheep: 48 hours.

Milk: Cattle: 12 hours.
Sheep: 12 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 concerns the neurotransmission involving sodium channels 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 toxic to fish and other aquatic organisms.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

None known.

5.2 Shelf life

Shelf-life of the veterinary medicinal product as packaged for sale: 36 months.

5.3 Special precautions for storage

Do not store above 25 °C.

5.4 Nature and composition of immediate packaging

High density polyethylene translucent dosing flasks, closed by two screw caps fitted internally with a compressible wad, containing 250 ml or 1 litre of pour-on.

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).

Not all pack sizes may be marketed.

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

Medicines should not be disposed of via wastewater or household waste.

Do not contaminate ponds, waterways or ditches with the product or empty container. The veterinary medicinal product should not enter water courses as deltamethrin may be dangerous for fish and other aquatic organisms.

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 Ireland Limited

7. MARKETING AUTHORISATION NUMBER(S)

VPA10996/103/001

8. DATE OF FIRST AUTHORISATION

01/10/1999

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

18/12/2024

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the [Union Product Database](https://medicines.health.europa.eu/veterinary) (<https://medicines.health.europa.eu/veterinary>).