Summary of Product Characteristics

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	
Formaldehyde 35 % solution	0.19 mg
Propylene glycol	160.0 mg

For the full list of excipients see section 6.1.

3 PHARMACEUTICAL FORM

Pour-on suspension.

4 CLINICAL PARTICULARS

4.1 Target Species

Cattle and Sheep.

4.2 Indications for use, specifying the target species

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

4.3 Contraindications

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

4.4 Special warnings for each target species

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.

4.5 Special precautions for use

Special precautions for use in animals
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 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 product or one of its components should avoid contact with the product. If you feel unwell after the use of the product, seek medical advice immediately and show the package leaflet or the label to the physician.

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

4.6 Adverse reactions (frequency and seriousness)

Hypersensitivity reactions can occur. In very rare cases following treatment, skin irritation with restlessness, heads tossing and tail flicking has been observed.
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).

4.7 Use during pregnancy, lactation or lay

No restrictions apply for use during pregnancy and lactation.

4.8 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.

4.9 Amounts to be administered and administration route

Route: For external topical use.
Apply the recommended dose by pouring it along the animals spine from the base of head to the tail. For sheep, it is recommended that the fleece is parted during administration.

Indications	*Dose Rate*
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.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

Overdose of twice the recommended treatment dose does not induce any adverse effects.

4.11 Withdrawal Period(s)

Meat and offal: Cattle: 18 days
Sheep: 48 hours

Milk: Cattle: 12 hours
Sheep: 12 hours

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Pyrethrins and pyrethroids.

ATCvet Code: QP53AC11.

5.1 Pharmacodynamic properties

Butox 7.5 mg/ml Pour-on 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.

5.2 Pharmacokinetic properties

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.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

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

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

6.2 Incompatibilities

None known.

6.3 Shelf-life

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

6.4 Special precautions for storage

Do not store above 25°C.

6.5 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.

6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials

Dangerous to fish and other aquatic life. Do not contaminate ponds, waterways or ditches with the product or empty container.
Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

Intervet Ireland Limited,
Magna Drive
Magna Business Park
Citywest Road
Dublin 24

8 MARKETING AUTHORISATION NUMBER(S)

VPA: 10996/103/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

30th September 2009

10 DATE OF REVISION OF THE TEXT

March 2014