SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Butox Swish, Pour-on Suspension 7.5 mg/ml

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance

Deltamethrin	7.5 mg/ml

Excipients

Formaldehyde solution 35%	0.19 mg/ml

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Pour on suspension.
Off-white homogenous suspension.

4. CLINICAL PARTICULARS

4.1 Target species

Cattle.

4.2 Indications for use, specifying the 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*, *Haematpoinus eurysternus*, and *Linognathus vituli*.

4.3 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.

4.4 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.

4.5 Special precautions for use

i. 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.

ii. 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.

iii. 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.

4.6 Adverse reactions (frequency and seriousness)

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).

4.7 Use during pregnancy or lactation

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, avoid the use of such organo-phosphorous insecticides (consult the supplier).

4.9 Amounts to be administered and administration route

For external use only.
Pour on the 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.

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

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

4.11 Withdrawal period(s)

Recommended withdrawal periods are as follows:

Meat and offal:	20 days
Milk:	Zero hours

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: pyrethroid ectoparasiticide for topical use

ATCvet code: QP53AC11

5.1 Pharmacodynamic properties

The 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.

5.2 Pharmacokinetic particulars

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.

5.3 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.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Formaldehyde solution 35%
Dispersing agent SI
Sodium lauryl sulphate
Silicon dioxide Precipitated
Rhodorsil 416
Rhodorsil 426R
Xanthan Gum
Citric Acid monohydrate
Propylene glycol
Purified Water

6.2 Major incompatibilities

None known.

6.3 Shelf life

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

6.4 Special precautions for storage

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

6.5 Nature and composition of immediate packaging

250 ml and 1 L high-density polyethylene translucent dosing flask, closed by two low density polyethylene screw caps fitted internally with a compressible wad. (“squeeze and pour" bottle).

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).

Not all pack sizes may be marketed.

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

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.

7. MARKETING AUTHORISATION HOLDER

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

8. MARKETING AUTHORISATION NUMBER

Vm 06376/4100

9. DATE OF FIRST AUTHORISATION

27 February 2004

10. DATE OF REVISION OF TEXT

December 2024

Gavin Hall
Approved: 09 December 2024