# SUMMARY OF PRODUCT CHARACTERISTICS

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Butox Swish, Pour-on Suspension 0.75% w/v

## 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

**Active substance**

| | |
|---|---|
| Deltamethrin | 0.750 g/100ml |

**Excipients**

| | |
|---|---|
| Formaldehyde solution 35% | 0.019 g/100ml |

For 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 Contra-indications

None

### 4.4 Special warning for each target species

None

### 4.5 Special precautions for use

i. Special precautions for use in animals

None

ii. Special precautions to be taken by the person administering the medicinal product to the animals

- Do not eat, drink or smoke while using the product.
- Wash hands and exposed skin before meals and after work.
- In case of contact with eyes and skin, wash immediately with water.
- In the event of accidental ingestion, seek medical advice immediately.
- Wear protective gloves when applying the product or handling recently treated animals.
- If clothing becomes heavily contaminated remove and wash before re-use.
- This product contains deltamethrin which may produce tingling, itchiness, and blotchy redness on exposed skin. If you feel unwell after working with this product, consult your doctor and show this label. Tell your doctor you have been using Butox Swish which contains deltamethrin.

Information for doctors: Advice on clinical management is available from National Poisons Information Service.

## 4.6 Adverse reactions (frequency and seriousness)

None observed.

## 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:**<br>Control of biting and nuisance flies | up to 100kg : 10 ml<br>100 – 300 kg : 20 ml<br>over 300 kg : 30 ml |
| **Lice:**<br>Control of biting and sucking lice | 10 ml per animal irrespective of weight. |

**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:
Edible tissues: 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.

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

2.5L 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 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

MSD Animal Health UK Limited
Walton Manor
Walton
Milton Keynes
Buckinghamshire
MK7 7AJ

## 8. MARKETING AUTHORISATION NUMBER

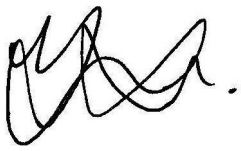
Vm 01708/4495

## 9. DATE OF FIRST AUTHORISATION

27 February 2004

## 10. DATE OF REVISION OF TEXT

July 2020



Approved: 03 July 2020