**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:**Control of biting and nuisance flies | up to 100kg : 10 ml100 – 300 kg : 20 mlover 300 kg : 30 ml |
| **Lice:**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**

* 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 AUTHORISAT**I**ON Number**

 Vm 01708/4495

**9. Date of first AUTHORISation**

27 February 2004

**10. Date of Revision of text**

 July 2020



Approved: 03 July 2020