

## SUMMARY OF PRODUCT CHARACTERISTICS

### 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Butox Protect 7.5 mg/ml pour-on suspension for cattle and sheep  
Deltamethrin

DK: Butoxvet 7.5 mg/ml pour-on suspension for cattle and sheep

SE: Blaze vet 7.5 mg/ml pour-on suspension for cattle and sheep

FI: Butox vet 7.5 mg/ml pour-on suspension for cattle and sheep

### 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

1 ml pour-on suspension contains:

**Active substance:**

Deltamethrin 7.50 mg

**Excipients:**

Formaldehyde solution 35 % 0.18 mg

For the full list of excipients, see section 6.1.

### 3. PHARMACEUTICAL FORM

Off-white to pale brown pour-on suspension

### 4. CLINICAL PARTICULARS

#### 4.1 Target species

Cattle, sheep

#### 4.2 Indications for use, specifying the target species

**Cattle:**

For the treatment and prevention of infestations with the following ectoparasites:

- sucking lice (*Linognathus vituli*, *Haematopinus eurytarnus*)
- biting lice (*Bovicola bovis*)

For the control of:

- stinging flies (*Stomoxys calcitrans*, *Haematobia spp.*) as well as nuisance flies (*Musca spp.*, *Hippobosca spp.*)

**Sheep:**

For the treatment and prevention of infestations with the following ectoparasites:

- sucking lice (*Linognathus ovillus*)
- biting lice (*Bovicola ovis*)
- sheep keds (*Melophagus ovinus*)

To avoid resistance, Butox Protect 7.5 mg/ml **pour-on** should only be used if the susceptibility of the local fly species to the active substance is assured.

### 4.3 Contraindications

Resistance to pyrethroids.

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

### 4.4 Special warnings for each target species

Animals should not be treated during heat-waves (danger of animals licking off the product).

Do not apply on or near the animal's eyes and mucous membranes.

Care should be taken to avoid practices like too frequent and repeated use of insecticides from the same class over an extended period of time, because they increase the risk of development of resistance and could ultimately result in ineffective therapy.

Butox Protect 7.5 mg/ml **pour-on** is a fly control product which will reduce the number of flies resting directly on the animal but it is not expected to eliminate all flies on a farm.

Cases of resistance to deltamethrin have been reported in stinging and nuisance flies in cattle and lice in sheep. Therefore, the use of this product should be based on local (regional, farm) epidemiological information about susceptibility of stinging and nuisance flies.

### 4.5 Special precautions for use

#### Special precautions for use in animals

Resistance cannot be ruled out in nuisance flies (*Musca* spp). Butox Protect 7.5 mg/ml pour on should be used in the context of a management concept to combat flies by improving the status of hygiene and the use of non-chemical substances primarily. In addition, the alternating use of insecticides of different active substance groups should be considered on the basis of a pest elimination program. The choice of the active substance should be based ideally on a susceptibility testing. Please ask your veterinary surgeon for further information.

Butox Protect 7.5 mg/ml **pour-on** 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 be already affected by infestation.

The presence of a mixed infestation should be established before treatment.

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

The presence of a mixed infestation with ectoparasites not indicated on the labelling should be established before treatment.

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

Irritation, sensitization, and adverse effects on the neuronal system might occur.

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

Wear protective gloves.

Change heavily contaminated clothes and wash before re-use.

Do not eat, drink or smoke while using Butox Protect 7.5 mg/ml pour on.

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

In case of contact with eyes, immediately rinse thoroughly with water.

People with known hypersensitivity to Butox Protect 7.5 mg/ml **pour-on** should avoid contact with the veterinary medicinal product.

If you feel unwell after the use of Butox Protect 7.5 mg/ml **pour-on** seek medical advice immediately and show the package leaflet or the label to the physician.

Deltamethrin is very toxic to dung insects. Potential long term effects should be considered for sequential treatments e.g. limitation on single treatment per season on the same pasture.

#### 4.6 Adverse reactions (frequency and seriousness)

Deltamethrin is locally irritant to eyes and mucous membranes.

Skin irritation (such as erythema or pruritus) along with restlessness, hyperactivity, anxiety or hypersensitivity and tossing heads and tails were observed in very rare cases after the drug administration.

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

##### Pregnancy:

Can be used during pregnancy.

##### Lactation:

Can be used during lactation.

#### 4.8 Interaction with other medicinal products and other forms of interaction

In combination with organo-phosphorous substances, the toxicity of deltamethrin is enhanced. Therefore, it is not advisable to use such products in combination with Butox Protect 7.5 mg/ml **pour-on**.

#### 4.9 Amounts to be administered and administration route

For pour-on use. Shake well before use.

For the 250 ml and 1000 ml bottles: screw on the applicator as described on the package insert.

For the 2500 ml bottle: connect applicator gun with attached tube and connection screw-cap.

Pour on the product evenly along the backline of the animals from the base of the head to the tail.

##### *Flies:*

##### **Cattle**

Up to 100 kg bodyweight: 10 ml Butox Protect 7.5 mg/ml **pour-on**

100 to 300 kg bodyweight: 20 ml Butox Protect 7.5 mg/ml **pour-on**

More than 300 kg bodyweight: 30 ml Butox Protect 7.5 mg/ml **pour-on**

##### *Sucking and biting lice as well as sheep keds:*

##### **Cattle, Sheep**

10 ml Butox Protect 7.5 mg/ml **pour-on** per animal

The following points have to be considered for the treatment of sheep:

- treat shortly after shearing (animals with short fleece)
- keep shorn group away from non-shorn animals
- shear and treat ewes 4-6 weeks before parturition

The veterinary medicinal product is administered as a single treatment.

However, treatment against flies can be repeated every 6-10 weeks, depending on the infestation degree. The duration of control for *Musca spp.* may vary.

The influence of weather on the duration of efficacy has not been investigated.

#### **4.10 Overdose (symptoms, emergency procedures, antidotes)**

Deltamethrin is of very low toxicity when administered topically as an aqueous suspension. Therefore, acute toxicity through transdermal absorption is not expected.

Overdoses of three times the recommended dose did not induce any adverse effects in cattle. An accidental oral intake of a large quantity or the existence of extensive skin lesions can lead to signs of toxicity such as salivation, excitement, clonic convulsions and paresthesias. A veterinarian should be consulted. The therapy has to be symptomatic and supportive.

#### **4.11 Withdrawal periods**

##### **Cattle:**

Meat and offal: 18 days

Milk: 0 days

##### **Sheep:**

Meat and offal: 1 day

Milk: 12 hours

### **5. PHARMACOLOGICAL PROPERTIES**

Pharmacotherapeutic group: pyrethroid ectoparasiticide for topical use

ATCvet code: QP53AC11

#### **5.1 Pharmacodynamic properties**

Deltamethrin is a synthetic pyrethroid which is, like other substances of this class, structurally based on naturally occurring plant pyrethrins.

Pyrethroids are insecticidal and acaricidal by contact. The target is the voltage-dependent sodium channel in the nerve membrane. The effect is prolonged opening of the sodium channels. The characteristic symptoms in arthropods are an initial period of excitement followed by coordination problems and, after a sufficient period of exposure, paralysis and death (killing effect).

#### **5.2 Pharmacokinetic particulars**

Due to its lipophilic nature, deltamethrin can accumulate in fat. The dermal absorption after use of a pour-on formulation is relatively minor. It is metabolised by ester hydrolysis, oxidation and conjugation. Non-metabolised deltamethrin is mainly excreted via the feces. The metabolites are mainly excreted via the urine. Only a minor part of deltamethrin is traceable in milk.

### **6. PHARMACEUTICAL PARTICULARS**

#### **6.1 List of excipients**

Formaldehyde solution (35%)

Sodium laurylsulphate

Silica, precipitated

Xanthan gum

Citric acid monohydrate

Propylene glycol

Rhodorsil 416

Rhodorsil 426R

Dispersing agent SI  
Purified water

## **6.2 Incompatibilities**

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

## **6.3 Shelf life**

Shelf-life of the veterinary medicinal product as packaged for sale: 36 months  
Shelf-life after first opening the immediate packaging: 30 weeks

## **6.4. Special precautions for storage**

Keep out of the sight and reach of children.  
Do not refrigerate or freeze. Protect from frost.

## **6.5 Nature and composition of immediate packaging**

250 ml and 1000 ml HDPE bottle in a carton box include an integrated dosing chamber and a screw-on applicator.  
2500 ml HDPE bottle packed with an applicator gun to be tube-connected to the bottle.

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**

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

Butox Protect 7.5 mg/ml **pour-on** should not enter water courses as this may be dangerous for fish and other aquatic organisms.

## **7. MARKETING AUTHORISATION HOLDER**

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

## **8. MARKETING AUTHORISATION NUMBER(S)**

## **9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

Date of first authorisation:> <{DD/MM/YYYY}><{DD month YYYY}>.>

## **10 DATE OF REVISION OF THE TEXT**

<{MM/YYYY}>

<{DD/MM/YYYY}>  
<{DD month YYYY}>

**PROHIBITION OF SALE, SUPPLY AND/OR USE**

Not applicable.