Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Bayticol 10 mg/ml Pour-On Solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active Substance
Flumethrin 10 mg

For a full list of excipients see section 6.1.

3 PHARMACEUTICAL FORM

Pour-on solution.

4 CLINICAL PARTICULARS

4.1 Target Species

Cattle

4.2 Indications for use, specifying the target species

For the control of ticks (*Ixodes ricinus*), biting lice (*Damalinia bovis*) and sucking lice (*Linognathus vituli, Haemotopinus eurysternus*) and psoroptic mange in cattle.

4.3 Contraindications

None.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

Special precaution(s) for use in animals:
None.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
Avoid contact with eyes, skin and mouth. Avoid breathing in the vapour. Avoid ingestion.
Do not eat, drink or smoke when using the product.
Wear protective gloves (disposable nitrile safety gloves) when applying the product or when handling recently treated animals.
In case of accidental spillage onto the skin wash with water and soap, in case of accidental spillage into the eyes or mouth, wash with plenty of water.
In case of spillage take off wet clothes, wash hands and skin thoroughly with soap and water.
Wash hands, exposed skin and face with water and soap after leaving the working area and before meals.

Additional protective clothes (long-sleeved shirt, long pants, boots and water resistant apron) are necessary if an amount of more than 10 litres of product is applied to animals per day.

4.6 Adverse reactions (frequency and seriousness)

Slightly irritant to the skin and mucous membranes.

4.7 Use during pregnancy, lactation or lay

Bayticol is safe to use in pregnant and lactating animals.

4.8 Interaction with other medicinal products and other forms of interactions

None known.

4.9 Amounts to be administered and administration route

Ascertain the weight of the animals to be treated. Squeeze the required dose volume into the dosemeter (provided) and apply the contents along the back line of the animal from the front of the shoulder to the tail setting.
Treat at 14 day intervals according to tick pressure.

Control of ticks and biting lice
1 mg/kg b.w. of the active ingredient equivalent to 1 ml of the solution for every 10 kg bodyweight.

Control of Sucking lice and mange
2 mg/kg b.w. of the active ingredient equivalent to 2ml of the solution for every 10 kg bodyweight.
In cases of clinically severe mange a repeat treatment is necessary after 14 days.
Bayticol may be used in beef and dairy cattle including pregnant animals.
All animals in the herd should be treated. Bought-in-animals should also be treated and yarded for some hours before joining the herd.

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

In trials 10 times the recommended dose rate (10 mg/kg b.w.) applied to calves did not cause any detectable side effects.

Symptoms of poisoning:- Ataxia, dyspnoea, apathy.
Treat symptomatically. Gastric lavage or saline laxative may be used.No data available on specific antidote.

4.11 Withdrawal period(s)

Animals must not be slaughtered for human consumption during treatment. Animals must not be slaughtered for human consumption until 5 days after the last treatment.Milk for human consumption may be taken only after 10 days following the last treatment.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Ectoparasiticides for topical use, pyrethroids
ATCvet code: QP53AC05

5.1 Pharmacodynamic properties

Flumethrin is an ectoparasticide of the synthetic pyrethroid group.
According to current knowledge the synthetic pyrethroids interfere with the sodium channel of nerve cell membranes, resulting in a delay in repolarization of the nerve. Alpha-cyano pyrethroids (type-II pyrethroids) like Flumethrin appear to be much more potent in this regard causing long-lasting trains of repetitive firing in nerve cells. In studies on the structure-activity relationship of a number of pyrethroids, interference with receptors of a certain chiral conformation was noted thereby causing selective activity on ectoparasites.
No anti-cholinesterase activity was noted with these compounds. Flumethrin was found to have an outstanding acaricidal activity.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

2-Octyldodecanol
Butylhydroxytoluene
Liquid paraffin

6.2 Major incompatibilities

None known.

6.3 Shelf-life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years.
Following withdrawal of the first dose, use remainder of the product within 9 months. Discard unused material.

6.4 Special precautions for storage

Do not freeze.
Store away from food and feed.

6.5 Nature and composition of immediate packaging

Container material: Polyethylene/polyamide bottles of litre.
Closure: Polypropylene screw closure, blue.
Contents: Viscous yellow-brown oil.
Dosemeter: Graduated polypropylene measuring cup with a polyethylene lid.

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

Product is toxic to fish, aquatic organisms and bees.
Do not contaminate ponds, streams or other waterways with unused product or empty containers.
Do not re-use the empty packaging container for any purpose.
Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements

7 MARKETING AUTHORISATION HOLDER

Elanco GmbH
Heinz-Lohmann-Strasse 4
27472 Cuxhaven
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8 MARKETING AUTHORISATION NUMBER(S)

VPA22020/060/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 01 October 1989
Date of last renewal: 30 September 2009

10 DATE OF REVISION OF THE TEXT

October 2020