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

Excipients:

Qualitative composition of excipients and other constituents
2-Octyldodecanol
Butylhydroxytoluene
Liquid paraffin

A clear solution.

3. CLINICAL INFORMATION

3.1 Target species

Cattle.

3.2 Indications for use for each target species

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

3.3 Contraindications

None.

3.4 Special warnings

None.

3.5 Special precautions for use

Special precautions for safe use in the target species:

Not applicable.

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 veterinary medicinal product.
Wear protective gloves (disposable nitrile safety gloves) when applying the veterinary medicinal 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 the veterinary medicinal product is applied to animals per day.

Special precautions for the protection of the environment:

The veterinary medicinal product is toxic to fish, aquatic organisms and bees.

3.6 Adverse events

Cattle

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Skin irritation, Inflamed mucosae.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or the national competent authority via the national reporting system. See the labelling for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy and lactation:

Can be used during pregnancy and lactation.

3.8 Interaction with other medicinal products and other forms of interaction

None known.

3.9 Administration routes and dosage

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.
The veterinary medicinal product 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.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

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.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance.

Not applicable.

3.12 Withdrawal periods

Cattle:
Meat and offal: 5 days.
Milk: 10 days.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QP53AC05

4.2 Pharmacodynamics

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.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

None known.

5.2 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.

5.3 Special precautions for storage

Do not freeze.
Store away from food and feed.

5.4 Nature and composition of immediate packaging

Container material: Polyethylene/polyamide bottles of 1 litre.
Closure: Polypropylene screw closure, blue.
Contents: Viscous yellow-brown oil.
Dosemeter: Graduated polypropylene measuring cup with a polyethylene lid.

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

Medicines should not be disposed of via wastewater or household waste.

The veterinary medicinal product should not enter water courses as flumethrin may be dangerous for fish and other aquatic organisms. Do not contaminate ponds, streams or other waterways with unused veterinary medicinal product or empty containers. Do not re-use the empty packaging container for any purpose.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Elanco GmbH

7. MARKETING AUTHORISATION NUMBER(S)

VPA22020/060/001

8. DATE OF FIRST AUTHORISATION

01/10/1989

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

14/08/2024

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).