

Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Poron SP 4 % w/v Pour-On Solution for Cattle

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Substance:

Permethrin tech. (cis 80: trans 20) 4.0 % w/v

Excipients:

For a full list of excipients see section 6.1

3 PHARMACEUTICAL FORM

Pour-on solution.

A clear straw-coloured non-aqueous solution.

4 CLINICAL PARTICULARS

4.1 Target Species

Cattle

4.2 Indications for use, specifying the target species

For the control of flies (particularly biting flies and horn-flies) and lice (including sucking and biting lice), and for the treatment of sarcoptic and chorioptic mange on cattle.

4.3 Contraindications

Do not treat calves under one week old.

4.4 Special warnings for each target species

Avoid the eyes when applying product to the head.

As with all insecticides, the degree of fly-killing and repellent activity afforded by Poron SP 4 % w/v Pour-On Solution for Cattle is influenced by prevailing weather conditions and the species of flies involved.

4.5 Special precautions for use

Special precaution(s) for use in animals

For external use only.

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

Wear protective clothing, rubber gloves and boots when applying the product.

Avoid contact with the eyes. If splashed in the eye, or on the skin, wash with plenty of clean running water immediately.

Wash hands and exposed skin before eating, drinking or smoking and after work.

Do not eat, drink, smoke whilst using the product.

Use in a well-ventilated area. Do not inhale the vapour.

4.6 Adverse reactions (frequency and seriousness)

None known.

4.7 Use during pregnancy, lactation or lay

Cattle producing milk for human consumption should be treated immediately after milking to allow as long an interval as possible (at least 6 hours) before the next milking.

4.8 Interaction with other medicinal products and other forms of interaction

Care should be taken when applying this product, as it may have an adverse effect on certain plastics.

Poron SP 4 % w/v Pour-On Solution for Cattle must be applied only with the Elanco Cattle Pour-On Gun as the product may have a detrimental effect on certain components of conventional dosing guns.

4.9 Amounts to be administered and administration route

Poron SP 4 % w/v Pour-On Solution for Cattle is a ready-to-use solution, which should be applied at the rate of 1ml per 10 kg bodyweight up to a maximum of 40ml.

Bodyweight	Dose
Calves up to 100kg	10ml
101 to 200kg	20ml
201 to 300kg	30ml
Over 300kg	40ml

The product should be applied using either the calibrated dispensing chamber incorporated into the 1 litre applicator bottle or the flexi-pack with an Elanco Cattle Pour-On Gun.

For fly and lice control.

Flies: Apply approximately one quarter of the calculated dose to the top of the head, the remainder should be applied along the neck and mid-backline.

A single dose is normally sufficient to control flies for up to 8 weeks. The first treatment should be carried out when the number of flies starts to increase. In cases of heavy infestation, the dose may be repeated at 4 week intervals.

Lice: Apply in the same way as the fly dosage. A single dose is normally sufficient to control all lice. In certain cases of heavy challenge, the dose may be repeated after 4 weeks.

Sarcoptic and chorioptic mange: The calculated dose should be applied directly to all visibly affected areas, any remaining should be poured along the backline in the normal way. The dose should be repeated after 4 weeks.

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

Toxic signs in mammals are tremors, hyperexcitability, salivation, choreoethetosis and paralysis. The signs disappear rapidly and the animals recover, generally within a week.

There is no specific antidote, but symptomatic therapy may be given if considered necessary.

4.11 Withdrawal Period(s)

Meat: Animals must not be slaughtered for human consumption during treatment. Cattle may be slaughtered for human consumption only after 7 days from the last treatment.

Milk: Cattle producing milk for human consumption should be treated immediately after milking to allow as long an interval as possible (at least 6 hours) before the next milking. There is no need to withhold milk from subsequent milkings.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Ectoparasiticides for topical use, including insecticides, permethrin.

ATCvet code: QP53AC04

5.1 Pharmacodynamic properties

Permethrin is a neuro-poison acting on the axons in the peripheral and central nervous system by interacting with sodium channels in insects.

5.2 Pharmacokinetic properties

Synthetic pyrethroids are generally metabolised in mammals through ester hydrolysis, oxidation and conjugation and there is a tendency to accumulate in tissues.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Butyl Dioxitol

6.2 Incompatibilities

None known

6.3 Shelf-life

Shelf-life of the veterinary medicinal product as packaged for sale: 2 years.

6.4 Special precautions for storage

Store in original container, tightly closed in a safe place.

Do not store above 25°C.

6.5 Nature and composition of immediate packaging

1 litre pack: a natural, high density polyethylene bottle with integral graduated dispensing chamber, closed with a white, urea screw cap and foil induction seal.

2.5 litre pack*: a white, opaque, high density polyethylene flexi-pack, closed with a white, polypropylene screw cap and foil induction seal.

* containing either 2.5 or 3 litres of product.

Not all pack sizes may be marketed.

6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials

Dangerous to fish.

Do not contaminate ponds, waterways and ditches with the licensed product or used container.

Wash out container thoroughly and dispose of safely.

Unused product or waste material should be disposed of in accordance with current practice for pharmaceutical waste under national waste disposal regulations.

7 MARKETING AUTHORISATION HOLDER

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8 MARKETING AUTHORISATION NUMBER(S)

VPA 10397/014/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 1st October 1998

Date of last renewal: 30th September 2008

10 DATE OF REVISION OF THE TEXT

June 2016