

Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Ectospec 2.5% w/v Pour-On Solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Substance

Cypermethrin Technical (93% w/w; cis/trans isomers 50 : 50) 2.5% w/v

For a full list of excipients see section 6.1.

3 PHARMACEUTICAL FORM

Pour-on solution.

An oily-based clear, pale yellow solution.

4 CLINICAL PARTICULARS

4.1 Target Species

Cattle.

4.2 Indications for use, specifying the target species

For control of lice and flies.

4.3 Contraindications

Do not treat calves under 7 days of age.

Do not use in cases of hypersensitivity to the active substance.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

Special precautions for use in animals

None.

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

Ectospec should be administered in a well-ventilated area. Protective clothing, including rubber gloves, should be worn and any accidental splashes should be washed off immediately.

Do not eat, drink or smoke when applying Ectospec. Wash hands and any exposed skin immediately after application has finished.

4.6 Adverse reactions (frequency and seriousness)

Occasionally, slight signs of discomfort may be observed in some cattle during the 48 hours following application. These side-effects are only temporary and have no long-term implications.

4.7 Use during pregnancy, lactation or lay

The active has a low oral activity and very little transdermal absorption is expected. To date there have been no reported complications in pregnancy or lactation.

4.8 Interaction with other medicinal products and other forms of interactions

It is not anticipated that Ectospec will interact with any of the medicines commonly administered to cattle.

4.9 Amounts to be administered and administration route

For topical administration as a pour-on

Lice control

A single 10 ml dose is normally sufficient to control lice. A few lice may survive on a small minority of animals. In cases of heavy challenge, if necessary, a repeat dose may be applied after 4 weeks.

Remove the cap from the chamber and gently squeeze the required amount into the chamber. Release the pressure from the container and pour as directed.

The 10 ml dose should be applied at an even rate along the backline from the crown of the head to the top of the rump.

Fly control

Apply a single 10ml dose at the onset of the fly season and repeat as necessary at 5 to 8 week intervals. Frequency of administration may, however, have to be varied depending on the level and type of infestation.

The 10 ml dose should be applied at an even rate along the backline from the crown of the head to the top of the rump.

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

Care should be taken not to overdose. Overdosing may invalidate the stated milk and meat withholding times as in 4.11 below.

4.11 Withdrawal period(s)

Meat and offal: 10 days

Milk: Zero hours. Cows should be treated immediately after milking to allow as long a time as possible to elapse before the next milking.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Ectoparasiticides for topical use, Pyrethrins and pyrethroids

ATCvet Code: QP53AC08

5.1 Pharmacodynamic properties

Cypermethrin is a synthetic pyrethroid insecticide used for both crop protection and to control ectoparasites on livestock.

Cypermethrin is a contact poison, having a rapid paralytic action on insects, preceded by muscular excitation and convulsions. The pyrethroids have sufficient stability to have a prolonged effect when applied to the animal.

Cypermethrin is not systemically active when used as a "pour-on" preparation. When applied in this manner, the product spreads over the surface of the animal.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Myritol
(Triglyceride, Medium Chain)

6.2 Major incompatibilities

Incompatible with alkali materials.

6.3 Shelf-life

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

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and composition of immediate packaging

High density polyethylene multi-dose 500 ml (with graduated measuring compartment) and 2.5L container. Each container is sealed with an aluminium tamper-evident seal and a plastic cap. Not all pack sizes may be marketed.

6.6 Special precautions for the disposal of unused veterinary medicinal products 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 used containers.

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

Bimeda Animal Health Limited
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8 MARKETING AUTHORISATION NUMBER(S)

VPA22033/014/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 11 July 1995
Date of last renewal: 16 April 2010

10 DATE OF REVISION OF THE TEXT

May 2019