IRISH MEDICINES BOARD ACT 1995

EUROPEAN COMMUNITIES (ANIMAL REMEDIES) (No. 2) REGULATIONS 2007

(S.I. No. 786 of 2007)

VPA: **10959/010/001**
Case No: 7005188

The Irish Medicines Board in exercise of the powers conferred on it by Animal Remedies (No. 2) Regulations (S.I. No. 786 of 2007) hereby grants to:

Bimeda Holdings PLC

Broomhill Road, **Tallaght**, **Dublin 24**, **Ireland**

an authorisation, subject to the provisions of the said Regulations and the general conditions of the attached authorisation, in respect of the Veterinary Medicinal Product:

Ectospec 2.5% Pour-On Solution

The particulars of which are set out in Part 1 and Part 2 of the said Schedule. The authorisation is also subject to any special conditions as may be specified in the said Schedule.

The authorisation,unless revoked, shall continue in force from **08/05/2009** until **10/07/2010**.

Signed on behalf of the Irish Medicines Board

_____

A person authorised in that behalf by the said Board.

(NOTE: This authorisation replaces any previous authorisation in respect of this product which is now null and void.)

Part II

Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Ectospec 2.5% 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.

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.

Not to be used in animals known to be hypersensitive to the active ingredient.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

Special precautions for use in animals

As per the special safety precautions to be taken by the person administering the product to animals listed in 4.11 below.

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 interaction

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)

Animals must not be slaughtered for human consumption during treatment. Treated animals should not be slaughtered for human consumption for a period of 10 days after treatment.

No withdrawal time is necessary for milk, although 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

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 Ph. Eur.)

6.2 Incompatibilities

Incompatible with alkali materials.

6.3 Shelf-life

2 years.

6.4 Special precautions for storage

Do not store above 25^{o}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. Both containers contain the relevant volume of an oily-based clear, pale yellow pour-on solution.

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

Dangerous to fish and other aquatic life.
Do not contaminate ponds, waterways or ditches with the product or used containers.

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

7 MARKETING AUTHORISATION HOLDER

Bimeda Holdings Plc.,
Broomhill Road,
Tallaght,
Dublin 24.

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10959/10/1

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

11th July 2005

10 DATE OF REVISION OF THE TEXT

8th June 2009