

IRISH MEDICINES BOARD ACT 1995

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

(S.I. No. 786 of 2007)

VPA: **10960/031/001**

Case No: 7006813

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:

Cross Vetpharm Group Ltd.

Broomhill Road, 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:

Cyperguard Concentrate for Dip Emulsion

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 **16/11/2009**.

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

Cyperguard Concentrate for Dip Emulsion

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active Substance:

Cypermethrin High Cis (80/20) 10 % w/w

Excipients:

For a full list of excipients see section 6.1.

3 PHARMACEUTICAL FORM

Concentrate for Dip Emulsion

This product appears as a clear, pale yellow liquid.

4 CLINICAL PARTICULARS

4.1 Target Species

Sheep

4.2 Indications for use, specifying the target species

For the prevention and treatment of blowfly strike, lice, keds and ticks on sheep by plunge dipping after dilution of the product with water. For the prevention and treatment of sheep scab caused by pyrethroid sensitive mites.

4.3 Contraindications

Do not use in cases of known hypersensitivity to the active ingredient.

4.4 Special warnings for each target species

Sheep should never be dipped on a full stomach, when the wool is wet or when they are heated, tired, thirsty or suffering from wounds or open sores.

Choose a cool dry day and dip early in the morning.

Rest sheep 2 or 3 hours before dipping.

Rams and fat sheep should be assisted through the baths and lambs dipped separately from the ewes.

Care should be taken to ensure that the sheep do not swallow or inhale any wash.

To avoid Post Dipping Lameness

Post dipping lameness may occur when the sheep are dipped in dirty wash, or wash which has been allowed to stand in the bath overnight or longer. It is important that the dip bath should be emptied and thoroughly cleaned at the end of each day's dipping or earlier if it becomes very dirty during the day's dipping.

4.5 Special precautions for use

Special precaution(s) for use in animals

After dipping, sheep should be allowed to stand in a bare open space under shade if possible but never in an enclosed building. For best results sheep should not be dipped soon after shearing but should have at least 3 weeks growth of wool.

Animals should not be dipped when they are heated, tired or thirsty.

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

Minimise operator contamination by good dipping facility design, e.g. fit splash boards where operators stand. Ensure that those using dips are competent to do so.

1. *When handling concentrate including dip replenishment:*

Do not use in an enclosed area and avoid inhaling vapour.

Wear non-lined, synthetic rubber gloves (heavy-duty gauntlet style nitrile at least 300mm in length and 0.5mm thick), wellington boots, waterproof (made of nitrile or PVC) trousers or leggings and coat or bib apron and a face shield when handling the concentrate.

Wash splashes of the dip concentrate from skin and eyes and from protective clothing and equipment immediately.

Remove heavily contaminated clothing immediately and wash or destroy.

2. *When working with diluted dips and freshly dipped sheep:*

Dipping should only be carried out in a well ventilated area, preferably outdoors.

Wear non-lined, synthetic rubber gloves (heavy-duty gauntlet style nitrile at least 300mm in length and 0.5mm thick), wellington boots, waterproof (made of nitrile or PVC) trousers or leggings and coat or bib apron.

Accidental splashes on exposed skin should be washed off immediately. Wash hands, face and exposed skin immediately after leaving the work area, removing protective clothing and washing hands, face and exposed skin.

Do not smoke, drink or eat during dipping without first withdrawing from the work area, removing protective clothing and washing hands, face and exposed skin.

Remove heavily contaminated clothing immediately and wash or destroy.

Check and replace any worn or damaged items of protective clothing. Wash measuring and dipping equipment after use. Protective clothing should be washed each day after dipping operations to prevent build up of chemicals in the materials.

3. *Handling sheep in the weeks following dipping:*

Handle sheep as little as possible after dipping as dip residues remain on the sheep for some weeks following dipping.

If you need to handle sheep, wear coveralls and wellington boots. If the sheep are wet, wear waterproof trousers and coat or bib-apron and wellington boots.

Always wash hands and exposed skin with soap and water after handling sheep or fleece and before eating, drinking and smoking.

4. *Medical Advice to users and doctors:*

Please note that Cyperguard is a non-organophosphorus sheep dip.

This product contains cypermethrin which is a synthetic pyrethroid. Cypermethrin is a potential skin sensitiser and may induce paraesthesia or tingling effects on exposed areas of human skin.

Wash all accidental spillages of the concentrate and diluted dip off the skin immediately. If you feel unwell after working with this product consult your doctor and show this label.

Doctors can obtain advice on clinical management from the Poisons Information Centre.

Harmful if in contact with skin and if swallowed. Irritating to eyes and skin.

4.6 Adverse reactions (frequency and seriousness)

Post dipping lameness may occur when sheep are dipped in dirty wash or wash that has been allowed to stand overnight.

4.7 Use during pregnancy, lactation or lay

No data are available to support the safe use in pregnant or lactating animals.

4.8 Interaction with other medicinal products and other forms of interaction

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

4.9 Amounts to be administered and administration route

(1) For Blowfly, Keds, Lice and Ticks

Initial Dilution Rate: 1 in 500
 Replenishment: 1 in 500

(2) For Sheep Scab

Initial Dilution Rate: 1 in 500
 Replenishment: 1 in 500

A single treatment will provide up to 9 weeks control of Blowfly Strike. Occasionally retreatment may be necessary after 4-9 weeks depending on the level of challenge, weather conditions and the timing of the first dipping.

Do not dilute the product until it is actually required.

To prepare the bath: Baths should be accurately calibrated. Fill the bath with the required quantity of clean water. Pour the required measured volume of dip directly into the bath to give the required strength. Stir the bath thoroughly from end to end to ensure complete mixing.

Replenishment: replenish after every 50 sheep dipped. The bath should be topped up to its original volume with water. Then add 20 ml of dip concentrate for each 10 litres of water added.

Dipping: Blowfly, Keds, Lice and Ticks: Immerse the sheep in the bath until the fleece is completely saturated with dip wash. All parts of the sheep except the head and ears must remain immersed for not less than thirty seconds. Plunge the head under at least twice, allowing time to breathe between plunges. To reduce the risk of Blowfly strike, control worms and treat all wounds.

Skim off at regular intervals any scum which may form on the surface of the dipping bath.

Sheep Scab: Cure and Prevention: For the purposes of dipping against sheep scab, sheep must be totally immersed in a sheep bath of an approved sheep dip, and all parts of the sheep except the head and ears must remain immersed in the bath for a period which shall in no case be less than one minute. Plunge the head under at least once.

To prevent fouling of the bath: It is important that the dip bath is emptied and thoroughly cleaned at the end of each day's dipping or earlier if it becomes very dirty during the days dipping. Dip no more than one sheep for every 2 litres of the initial bath volume before the bath is completely emptied.

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

Tolerance studies at 2.5 times the recommended dosage rate indicated excellent tolerance by the target species.

Care should be taken not to overdose. Overdosing may invalidate the stated meat withholding times.

In the case of overdosing, treatment should be symptomatic.

4.11 Withdrawal Period(s)

Animals must not be slaughtered for human consumption during treatment.

Meat and offal: 14 days.

Not for use in sheep producing milk for human consumption.

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 excitations and convulsions. The pyrethroids have sufficient prolonged stability on the animal to have a knockdown and kill effect on insects.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

N-methyl 2 pyrrolidone
N-octyl 2 pyrrolidone
Ethoxylated Castor Oil
Pluronic L131
Rhodafac RS 710

6.2 Incompatibilities

Do not mix the product with other medicinal product.

6.3 Shelf-life

Shelf-life of the veterinary medicinal product as packaged for sale: 2 years.
Any unused diluted product should be discarded after the day's dipping.

6.4 Special precautions for storage

Store below 25°C. Protect from light.
Store in the original container. Keep the container tightly closed.

6.5 Nature and composition of immediate packaging

Multilayered plastic containers with an internal polyamide layer in 1 L, 2 L and 5 L sizes. The containers are sealed with a tamper evident polyethylene screw-cap which has a tear off locking flange.

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 water including ponds, ditches, ground and surface waters. It is an offence to permit any poisonous, noxious or polluting matter to enter any river, stream or watercourse.

In order to protect aquatic life, it is important to ensure that sheep have an area where they can dip from the fleece and drain back into the bath immediately after dipping and also to ensure that sheep do not enter or cross watercourses whilst the fleece is still wet. Do not dip sheep near a watercourse.

Empty containers should not be re-used. Wash out thoroughly and place rinsings into the dip bath. Dispose of containers by approved means.

Only buy sufficient product for immediate use. Do not dispose of the dip concentrate on the farm. Any undiluted product should be disposed of by a reputable specialist waste disposal contractor.

The spent dip wash should be disposed of by a reputable waste disposal contractor. If you have a suitable area of land, you may apply not more than 5000 litres of used dip per hectare (450 gallons/acre).

7 MARKETING AUTHORISATION HOLDER

Cross Vetpharm Group Ltd.,
Broomhill Road,
Tallaght,
Dublin 24.

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10960/031/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

14th May 2008

10 DATE OF REVISION OF THE TEXT

16th November 2009