

IRISH MEDICINES BOARD ACT 1995

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

(S.I. No. 786 of 2007)

VPA: **10835/005/001**

Case No: 7007553

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:

Novartis Animal Health Ireland Ltd

Industrial Park, Cork Road, Waterford

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:

Robust 10% Dip Concentrate.

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 **29/03/2010** until **29/03/2010**.

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

Robust 10% Dip Concentrate.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Substance

Cypermethrin (tech) (cis trans/ 80:20) 10% w/v

Excipients

A mixture of solvents and emulsifiers.

3 PHARMACEUTICAL FORM

Dip concentrate.

4 CLINICAL PARTICULARS

4.1 Target Species

Sheep.

4.2 Indications for use, specifying the target species

For use on sheep as a plunge dip after dilution of the product with water. For the control of blowfly strike. For the treatment and control of lice, ticks and keds. For the control of scab caused by pyrethroid sensitive mites. Provides 4 weeks protection against scab re-infestation following a single dipping.

4.3 Contraindications

Do not treat sheep when they are heated, tired or thirsty.

4.4 Special warnings for each target species

None known.

4.5 Special precautions for use

For external use only.

Dangerous to fish and other aquatic life. Do not contaminate water including ponds, ditches, ground and surface waters.

For best results sheep should not be dipped soon after shearing, but should have at least 3 weeks growth of wool.

After dipping, sheep should be allowed to stand in a bare, open space, under shade if possible but never in an enclosed building.

Do not dilute the product until it is actually required.

Keep out of reach of children.

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

When handling concentrate including dip replenishment:

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

Wash splashes of the dip concentrate from the skin and eyes and from protective clothing and equipment immediately. Do not use in an enclosed area and avoid inhaling the vapour. Remove heavily contaminated clothing immediately and wash or destroy.

When working with diluted dips and freshly dipped sheep:

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

Wash hands, face and exposed skin immediately after leaving the work area, eg. after dipping or for meal breaks. Accidental splashes on exposed skin should be washed off immediately. Do no 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.

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

Dipping should only be carried out in a well-ventilated area, preferably outdoors. Avoid use in still-air conditions.

4.6 Adverse reactions (frequency and seriousness)

None known.

4.7 Use during pregnancy, lactation or lay

The product must not be used on sheep producing milk for human consumption.

4.8 Interaction with other medicinal products and other forms of interaction

Do not mix with any other product.

4.9 Amounts to be administered and administration route

For Blowfly Control & Scab

Initial Dilution Rate : 1 litre dip to 400 litres water.

Replenishment : 1 litre dip to 300 litres water after 10% depletion in volume.

Controls scab and gives 4 weeks protection against re-infestation following a single dipping. Controls blowfly strike for 8 - 10 weeks.

For Blowfly Strike Only:

Initial Dilution Rate : 1 litre dip to 800 litres water.

Replenishment : 1 litre dip to 500 litres water after 10% depletion in volume.

Controls blowfly strike for 6 - 8 weeks.

Lice, Ticks & Keds:

Initial Dilution Rate : 1 litre dip to 1000 litres water.

Replenishment : 1.5 litres dip to 1000 litres water (equivalent to 1litre dip to 660 litres water) after 10% depletion in volume.

To prepare the bath : The first essential is to know the capacity of the bath. Fill the bath with the required quantity of clean water. Pour the 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 the volume of the bath has fallen by no more than 10%. Replenish at the required rate.

Hard Water : Hard water should be softened before use with the dip. Use 1 kg washing soda to each 500 litres water. Allow softened water to stand for 2-3 hours before mixing with the dip.

Dipping:

Immerse the sheep in the bath until the fleece is completely saturated with dip wash. Plunge the head under at least twice, allowing time to breath between plunges. When dipping for scab all parts of the sheep except the head and ears must remain immersed for not less than one minute. Skim off at regular intervals any scum which forms on the surface of the bath.

To prevent fouling of the bath:

Serious fouling of the bath can be avoided if no more than one sheep is dipped for every 2 litres of the initial bath volume before the bath is completely emptied and refilled with fresh wash.

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

Toxic signs in mammals are tremors, hyperexcitability, salivation, choreoathetosis and paralysis. The signs disappear rapidly and the animals recover, generally within a week. There is no specific antidote but symptomatic therapy can be given if considered necessary.

4.11 Withdrawal Period(s)

Meat : Nil.

Milk : Not for use in sheep producing milk for human consumption.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Cypermethrin is a neuropoison acting on the axons in the peripheral and central nervous system by interacting with sodium channels in insects. Synthetic pyrethroids are generally metabolised in mammals through ester hydrolysis, oxidation and conjugation and there is no tendency to accumulate in tissues.

5.1 Pharmacodynamic properties

5.2 Pharmacokinetic properties

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

6.2 Incompatibilities

Do not mix with any other product.

6.3 Shelf-life

24 months.

Do not store diluted dipwash overnight. Discard the diluted product after the days dipping.

6.4 Special precautions for storage

Store in original container, tightly closed, in a safe place under lock and key.

Keep in a store designed for the storage of approved pesticides.

Do not store above 25⁰C. Protect from frost.

6.5 Nature and composition of immediate packaging

A straw-coloured emulsifiable dip concentrate contained within a 1, 2, 2.5 or 5 litre mild steel drum, closed with a steel plug insert and screw cap.

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

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

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

If you have a suitable area of land, the spent dip wash may be disposed of by applying no more than 5000 litres per hectare (450 gallons/acre), making sure that it cannot enter rivers, streams or lakes by run off. Remove livestock from the land before spreading. Alternatively, the spent dip wash should be disposed of by a reputable waste disposal contractor.

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

Fisheries Acts 1959 to 1980 and Local Government (Water pollution) Act, 1977.

As these preparations are highly injurious to fish and stream life, care should be taken to prevent them entering rivers and streams, and users are warned that it is an offence to permit the entry or discharge into any water of any deleterious matter liable to render the water poisonous or injurious to fish, spawning grounds or the food of any fish.

7 MARKETING AUTHORISATION HOLDER

Novartis Animal Health Ireland Ltd.
Industrial Park
Cork Road
Waterford
Ireland

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10835/005/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

30th March 2005

10 DATE OF REVISION OF THE TEXT

3rd March 2010