IRISH MEDICINES BOARD ACT 1995

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

(S.I. No. 786 of 2007)

VPA: **10835/004/001**
Case No: 7007537

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:

Crovect 1.25% 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 **07/04/2010** until **21/09/2010**.

Signed on behalf of the Irish Medicines Board

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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

Crovect 1.25% Pour-On Solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substances		
Cypermethrin tech. (cis:trans/ 80:20)	1.25%	w/v
Excipients		
Green S dye (E142)	0.02%	w/v
Butyl dioxitol	to	100%

3 PHARMACEUTICAL FORM

Pour-on solution.

4 CLINICAL PARTICULARS

4.1 Target Species

Sheep.

4.2 Indications for use, specifying the target species

For the treatment and control of ticks, headflies and biting lice in sheep.
For the prevention and treatment of blowfly strike in sheep.

4.3 Contraindications

Not to be used in lambs less than one week old.
For the prevention of blowfly strike; do not administer to animals of less than 12.5 kg bodyweight.
Do not use in cases of known hypersensitivity to the active ingredient.

4.4 Special warnings for each target species

See point 4.5

4.5 Special precautions for use

Avoid treating very young lambs if the weather is unseasonably hot.
Crovect Pour-On minimises mothering-up problems after treatment.
However, care must be taken not to apply the product right to the lamb's tail, as a ewe recognises a young lamb partly by the smell of the tail area.
Blowflies are attracted by dirty, damp wool or open wounds.
The more common site for fly strike is the rump due to soiling caused by diarrhoea and urine staining.
The efficacy of Crovect Pour-On is reduced in the presence of spoiled or dirty wool.
Therefore, sheep must be crutched (dagged) regularly and appropriate worm control measures employed.
Take care not to apply product in the sheep's eyes.
This precaution should be observed particularly when treating breeds with little wool on their heads.
Full operating and maintenance instructions, including details on the use of nozzles are supplied with each applicator gun.
Please read carefully before use.
Maintain applicator gun carefully to ensure accurate dosage.

For external use only.

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

Butyl dioxitol is slightly irritating to skin and moderately irritating to eyes
Wear protective clothing, rubber gloves and boots when applying the product.
Wear a dust mask when applying as a fan-spray for the prevention of blowfly strike.
Wash splashes from skin and eyes immediately.
Do not eat, drink or smoke whilst using the product.
Wash hands and exposed skin after contact with the product and before eating, drinking or smoking.
Use in a well-ventilated area.
In a few instances operators may experience a mild tingling sensation of the face when using this product.
Avoid handling sheep immediately after treatment.

4.6 Adverse reactions (frequency and seriousness)

Transient adverse effects may occur. These include irritation, ataxia, incoordination and flaccid semi-paralysis.
In most of the reported literature studies and toxicity trials these signs disappeared fairly rapidly and the animals generally recovered within a week.
The most severe side effects were observed in very young lambs (1-2 days old) and Crovect Pour-On is therefore contra-indicated in lambs less than one week old.

4.7 Use during pregnancy, lactation or lay

Whilst there is no specific data available on the use of Crovect Pour-On in pregnant ewes, laboratory studies (in rats and rabbits) have shown that cypermethrin has no teratogenic or mutagenic effect.
The product must not be used in sheep producing milk for human consumption.

4.8 Interaction with other medicinal products and other forms of interaction

Crovect Pour-On must be applied only with the recommended applicator 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

Crovect Pour-On is administered by means of an endecto applicator gun as follows:

Lice: 5 ml per 20 kg bodyweight up to a maximum of 20 ml.

Bodyweight	Dose	Doses per litre
Up to 20 kg	5 ml	200
21 to 40 kg	10 ml	100
41 to 60 kg	15 ml	66
Over 60 kg	20 ml	50

Using the straight nozzle on the applicator gun, apply as a pin-stream from the shoulders to the rump along the middle of the backline.
Sheep may be treated off-shears or at any time during the year.

Ticks: Adult sheep and lambs over 10 kg: 10 ml per 20 kg bodyweight, up to a maximum of 40 ml.
Lambs under 10 kg: 5 ml followed 3 weeks later by a 10 ml application.

Bodyweight	Dose	Doses per litre
Up to 10 kg	5 ml	200
11 to 20 kg	10 ml	100
21 to 40 kg	20 ml	50
41 to 60 kg	30 ml	33
Over 60 kg	40 ml	25

Using the straight nozzle on the applicator gun, apply as a pin-stream from the crown of the head to the top of the rump.

Headflies: 5 ml per animal irrespective of size.
Apply to the top of the head between the ears using the T-bar nozzle.
Take care not to apply product in the sheep's eyes.
One application of Crovect Pour-On before the start of the headfly season will give up to 4 weeks protection.
Re-treat as required.

Blowflies:

Prevention of blowfly strike

Bodyweight	Dose	Doses per litre
Up to 25 kg *	20 ml	50
25 to 40 kg	30 ml	33
Over 40 kg	40 ml	25

* Do not administer to animals of less than 12.5 kg bodyweight
Apply as a fan-spray to the surface of the fleece on the back and hindquarters of the sheep using the applicator gun fitted with the fan-spray nozzle.
Half the dose should be applied to the shoulders, back and flanks, and half to the rump. The distance between the nozzle and the fleece should be approximately 20 cm.
Each dose will require 2 or 3 sweeps to apply.
THE PRODUCT WILL PREVENT BLOWFLY STRIKE ONLY ON AREAS COVERED BY SPRAY.
One application will give 6-8 weeks protection. Re-treat as required.

Treatment of blowfly strike

Apply directly to the affected parts at the rate of 2.5 ml per 100 - 150 cm^2 (roughly the size of a hand).
The T-bar nozzle should be used.

Most strikes will require 5 - 10 ml. Ensure that the affected parts are treated.
A single application is sufficient to ensure that larvae are expelled and killed within a few hours.

This product contains a blue dye to aid in the identification of treated animals.
The colour is temporary and will fade from the fleece within 7 days of application,
depending upon fleece length and weather conditions.

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

Toxic signs in mammals are tremors, hyperexcitability, salivation, choreoathetosis and paralysis,
rarely leading to death.
Usually, 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: Animals must not be slaughtered for human consumption during treatment. Sheep may be slaughtered for human consumption only after 7 days from the last treatment.
Milk: Not to be administered to animals producing milk for human consumption.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Mechanism of action

Cypermethrin is a neuropoison acting on the axons in the peripheral and central nervous system by interacting with sodium channels in insects.

Pharmacokinetics

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

None known.

6.3 Shelf-life

24 months.

6.4 Special precautions for storage

Store in original container, tightly closed in a safe place.
Do not store above 25^{o}C.
Protect from light.
Store away from food, drink and animal feeding stuffs.

6.5 Nature and composition of immediate packaging

A blue-coloured non-aqueous solution contained within a white, opaque, high density polyethylene flexi-pack of 2.5 or 5 litre capacity, closed with a white, polypropylene screw cap and surlyn coated foil induction seal.

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

Harmful to fish. Harmful to aquatic invertebrates and may have harmful effects to dung fauna and insects.
Do not contaminate ponds, waterways and ditches with the product or used container.
Wash out container thoroughly.
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

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

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10835/004/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

22nd September 2005

10 DATE OF REVISION OF THE TEXT

3rd March 2010