

IRISH MEDICINES BOARD ACT 1995

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

(S.I. No. 786 of 2007)

VPA: **10277/085/001**

Case No: 7007310

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:

Schering Plough Limited

Shire Park, Welwyn Garden City, Hertfordshire AL7 1TW, United Kingdom

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:

Coopers Ectoforce Sheep Dip

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 **19/02/2010**.

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

Coopers Ectoforce Sheep Dip

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Substance

Diazinon (Dimpylate) Stabilised Technical 60% w/w

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Dip Emulsion.

A clear 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, Keds, Lice, Ticks and Scab infestations.

4.3 Contraindications

Do not use if under medical advice not to work with organophosphorous products.

Not suitable for use on sheep that are being milked for human consumption.

4.4 Special warnings for each target species

Sheep should not be dipped when their fleece is already wet, or when they are tired, thirsty, or heat stressed.

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 bath 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 days dipping.

4.5 Special precautions for use

Special precaution(s) for use in animals

See section 4.4.

For external use only

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

Before Dipping

Read instructions on carton before use.

Use Tear Strip to open the foil bag. **DO NOT** use scissors, a knife or any sharp implement.

Do not use product if liquid has leaked from the water soluble sachet into the clear protective pouch. Instead take it back, in its original packaging, to where you bought it.

Product should be used immediately after opening the clear protective pouch.

Protective clothing must be worn when handling the product packaging and when opening the pack.

Prior to use store in original container.

Always cover the bath when not in use, and take action to prevent accidents to both humans and 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.

DIAZINON is an ORGANOPHOSPHORUS compound. Do not use if under medical advice not to work with such compounds. If you have previously felt unwell after using a product containing an organophosphorus compound, consult your doctor before working with this product and show the doctor the product label.

Use only in a dip bath that is well designed and hazard free.

Check that all those involved in dipping operations are adequately trained and competent.

Keep children well away from all dipping operations.

Make sure that everyone has the recommended protective clothing and insist that they wear it. Ensure you have spare protective clothing available in case any items become damaged.

The recommended protective clothing is:-

Face Shield (when handling dip concentrate)

Bib apron (over boiler suit) or waterproof coat (PVC or nitrile)

Gloves (Non-lined or flock-lined, PVC or nitrile, heavy duty gauntlet style – 0.5 mm thick and at least 300 mm long)

Waterproof leggings/trousers (PVC or nitrile to be worn outside your boots)

Wellington boots

During and Immediately After Dipping:

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

Before leaving the work area wash and remove protective clothing and do **not** smoke, drink, eat or use the toilet during dipping operations.

Always wash hands, face and exposed skin immediately after leaving the work area.

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

Immediately wash off sheep dip particularly dip concentrate, if it gets on your skin or in your eyes.

Immediately remove heavily contaminated clothes and wash contaminated areas of skin – see further instructions below under “**MEDICAL ADVICE TO USERS**”. Wash or destroy heavily contaminated clothes immediately.

Medical Advice to users:

If you feel unwell after using this product consult your doctor and show your doctor the label. Treat any cases of heavy contamination as an emergency. You should go straight to hospital after removing contaminated clothing, and rinse with plenty of water areas of skin which came into contact with sheep dip.

If sheep dip has been swallowed go straight to hospital and take the label with you.

Handling sheep in the weeks following dipping:

It is good practice not to shear sheep in the 3 months after dipping.

Handle sheep as little as possible after dipping as dip residues remain on the sheep for some weeks. If you need to handle sheep, wear coveralls and Wellington boots. If the sheep are wet also wear waterproof trousers and coat.

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

Medical Advice to Doctors

Poisoning from organophosphorus compounds in sheep dips results from blockage of acetylcholinesterase, with a resultant over-activity of acetylcholine.

Symptoms include headache, exhaustion and weakness, mental confusion together with blurred vision, excessive salivation and sweating, cramp-like abdominal pain, chest tightness, diarrhoea, constricted pupils, and bronchorrhoea. These may develop for up to 24 hours after exposure.

Severe poisoning can include general muscle twitching, loss of co-ordination, extreme difficulty with breathing and convulsions which may lead to unconsciousness in the absence of medical treatment. Treat symptomatically and seek urgent hospital transfer if poisoning is suspected.

Advice is available from the National Poisons Information Services Centres.

Other precautions - environmental warnings

Dangerous to fish and other aquatic life. Harmful to game, wild and domestic birds and mammals.

Store in original packs, in a safe place, under lock and key. Keep in a store designed for the storage of approved pesticides.

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.

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.

Do not use soakaways as a means of disposal. If you have a suitable area of land, you should apply no more than 5,000 litres of dipwash per hectare (450 gallons/acre). Dilution of 1 part dip by 3 parts or more of water or slurry may be necessary to achieve this application rate if using equipment such as a slurry tanker. Alternatively, the spent dipwash should be disposed of by a reputable waste contractor.

Consult the following for further advice on safe disposal:

Fisheries Acts, 1959 to 2001 and Local Government (Water Pollution) Acts, 1977 and 1990. As this preparation is extremely dangerous to fish and stream life, care should be taken to prevent any of it 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.

4.6 Adverse reactions (frequency and seriousness)

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

See also 4.4

4.7 Use during pregnancy, lactation or lay

There have been no reported complications in pregnancy or lactation.

Not suitable for use on sheep that are being milked for human consumption.

If dipping of pregnant sheep is essential, they should be gently lowered into the bath and assisted out.

4.8 Interaction with other medicinal products and other forms of interaction

Not to be mixed with any other dip.

As this is an organophosphorus sheep dip, an interval of at least 14 days should elapse between dipping and dosing with any drench, etc. containing levamisole or an organophosphorus compound.

4.9 Amounts to be administered and administration route

To prepare the bath:

1. Check that the bath is clean and only use clean water. Prepare the bath and mix in the dip concentrate on the day of dipping. Use a container of known volume to calibrate the capacity of the bath.
2. Fill the dip bath with water to the accurately calibrated level. To prevent overspill **do not fill the bath to capacity** and make sure you allow for water displacement by the sheep. Surge baffles can help prevent spillage.
3. Follow the instructions for dispensing the dip safely.
4. **Initial fill**

The treat sheep scab, blowfly strike, keds and lice the product must be used at a concentration of 0.04% w/w diazinon. This concentration of diazinon is achieved by adding the required number of 100 ml packs to the dip bath. The required number of packs can be calculated as follows or by using the dip calculator provided with the product:

Number of packs to add to the dip bath	
Bath capacity	Number of 100 ml packs
450 litres (100 gallons)	3
900 litres (200 gallons)	6
1800 litres (400 gallons)	12
2250 litres (500 gallons)	15

Once you have calculated the number of 100ml packs you require then follow these directions:

Remove the aluminium foil bags from the pack. Open the bags by way of the tear strip at the top of each bag. **Do not use scissors, a knife or any sharp implement to open the bag.** Remove the inner pouch from each bag and place it carefully on a dry, flat, surface near the dip.

Before opening the pouch visually examine it for leakage of product from the inner water soluble sachet. Should there be leakage into the pouch then under **NO circumstances should the pouch be opened but instead take the entire pack back to where you bought it.**

Open each pouch using the tear strip. **Do not use scissors, a knife or any sharp implement to open the pouch.**

Keeping the pouch with the open end uppermost go immediately to the dip bath, invert the pouch and drop the inner water soluble sachet into the dip bath at a distance from the water surface of no more than 6 inches. This is to prevent splashing. Hold the handle of the pouch while you drop the sachet into the dip bath. It is important that you do not touch the water soluble sachet and that it does not come into contact with water before it goes into the dip bath as this could cause it to dissolve prematurely.

Continue to add all the required number of sachets to the dip bath in the same manner. The water soluble sachets will float on the surface of the dip bath and may take up to 5 minutes to release the product depending on water temperature. **Do not** attempt to hasten the process by touching the sachets. Dipping should not proceed until the sachets have fully dissolved and the dip has been thoroughly mixed. Mixing will ensure immediate dispersion and complete dissolution of the remains of the sachets.

To replenish the bath:**Baths of less than 2250 litres (500 gallons)**

Add 200 ml (2 x 100ml packs) of dip after every 40 sheep dipped and fill the bath with water to its original level.

Baths of 2250 litres (500 gallons) or more

Add 500 ml (5 x 100ml) of dip after every 100 sheep dipped and fill the bath to its original level.

When adding the required number of packs to the dip bath follow the same directions as for the **Initial Fill**.

5. **After at least 5 minutes** have elapsed and the sachets have released the product, **mix the dip** by stirring thoroughly with a metal rod, preferably with a paddle attachment. **Always remember to mix both after the initial fill and after each replenishment.** You may now commence dipping your sheep.
6. For **sheep scab** all parts of the animal, except the head and ears, should remain under the dip wash mixture for **at least a minute.**
7. Plunge the head under at least twice, allowing time for the animal to breathe between plunges.
8. For **blowfly strike, ticks, keds and lice** infestations, animals should remain in the dip bath for at least half a minute and the head should be plunged once.
9. After dipping, all sheep should stand in draining pens for not less than 10 minutes or until they have completely stopped dripping.
10. If large amounts of scum form on the surface of the bath skim it off and place in a secure container. This must be clearly marked and disposed of safely (see **“DISPOSAL”** below).
11. Fouling of the dip wash reduces dip effectiveness. Therefore, **do not dip more than 1 sheep per 2 litres of dip wash** that was in the bath at the start of dipping. For example, if the total volume of wash in your dip bath was 1000 litres (220 gallons) you should not dip more than 500 sheep **no matter how many times you have replenished and topped-up the bath (see above).** You should then empty, clean and recharge the bath with fresh dip wash.
12. Post-dipping lameness may occur when sheep are dipped in dirty wash or in wash that has stood overnight.
13. Sheep should have at least three weeks growth of wool after shearing when they are dipped, to obtain good residual protection.
14. To control **ticks**, dip ewes in spring before lambing. If the infestation is severe, dip again 6 weeks later (excluding young lambs). Hogs and other sheep should be dipped as soon as possible after ticks appear.

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

Care should be taken not to overdose.

4.11 Withdrawal Period(s)

Animals intended for human consumption must not be slaughtered during treatment.

Sheep intended for human consumption may only be slaughtered from 35 days after the last treatment.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Diazinon is an organophosphorus compound. It is effective against a wide range of insects. Organophosphorus insecticides are both contact and stomach poisons. They act by combining with the neutralising cholinesterase at the nerve ganglion of the insect. Cholinesterases remove acetylcholine. Two types of this enzyme are recognised, the first, true acetylcholinesterase, is largely specific in its action and is found mainly in erythrocytes, in muscles and in the nervous system. The second, pseudocholinesterase, a non-specific enzyme capable of hydrolysing a wide variety of esters, occurs in plasma and the nervous system. Some organophosphorus compounds inhibit one of these enzymes more than the other but few are entirely specific. Owing to their liquid solubility, they are rapidly absorbed. Used as a sheep dip at a concentration of 0.025%, Diazinon is active locally in the skin and wool.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Emulsogen IT
Shellsol R

6.2 Incompatibilities

Not to be mixed with any other dip.

Incompatible with copper sulphate and its solutions.

6.3 Shelf-life

Shelf-life of the veterinary medicinal product as packaged for sale: 36 months.

6.4 Special precautions for storage

Do not store above 25°C.
Store in original package.

6.5 Nature and composition of immediate packaging

Primary pack: PVOH Water Soluble Sachet – 100 ml

Secondary pack: PAO/PE 15/50 Laminated Film pouch to hold a single 100 ml sachet.

Tertiary pack: Aluminium barrier foil bag to hold single pouch.

Display carton: Printed, corrugated carton with self-closing lid to hold 5 x 100 ml bags.

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

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.

Do not dispose of the dip concentrate on the farm. Any unwanted product should be disposed of by a reputable specialist waste disposal contractor.

If you have a suitable area of land the spent dip wash may be disposed of by applying no more than 5,000 litres/hectare (450 gallons/acre). Dilution of 1 part dip by 3 parts or more of water or slurry may be necessary to achieve this application rate if using equipment such as a slurry tanker. Alternatively, the spent dipwash should be disposed of by a reputable waste contractor.

7 MARKETING AUTHORISATION HOLDER

Schering-Plough Ltd.,
Schering-Plough House,
Shire Park,
Welwyn Garden City,
Hertfordshire, AL7 1TW,
England.

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10277/85/1

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

1st November 2006

10 DATE OF REVISION OF THE TEXT

19th February 2010