1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Winter Dip 100 mg/ml Concentrate for dip emulsion for sheep

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substances:

Diazinon (Dimpylate) 100 mg/ml.

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Multisol H585 (hydrocarbon solvent)	750 ml/l
Sermul EA 88	
Ethylan NS-500LQ	
Soya Bean Oil (epoxidised)	

A clear pale-yellow emulsifiable dip concentrate.

3. CLINICAL INFORMATION

3.1 Target species

Sheep.

3.2 Indications for use for each target species

For the treatment and control of sheep scab (*Psoroptes ovis*) and blowfly strike.

3.3 Contraindications

Do not use on sheep producing milk for human consumption.
Do not use in cases of hypersensitivity to the active substance or to any of the excipients.

3.4 Special warnings

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 bath and lambs dipped separately from ewes.

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

Post dipping lameness caused by bacterial build up may occur when the sheep are dipped in dirty wash, or wash that has been allowed to stand over-night. It is important that dip wash is not retained for a second day's dipping. Prepare the bath and dip following detailed instructions.

3.5 Special precautions for use

Special precautions for safe use in the target species:

Prepare the bath and dip following detailed instructions. Ensure the bath and water is clean before starting to dip. This product does not contain a bacteriostat. If the bath is allowed to become too fouled, bacterial infection could become a problem. Monitor the sheep on the days following dipping and seek veterinary advice if necessary.

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

Diazinon (Dimpylate) is an organophosphorous compound. Do not use this product if under medical advice not to work with organophosphorous compounds.

WINTER DIP MUST BE USED IN ACCORDANCE WITH THE DISPENSING INSTRUCTIONS PROVIDED USING THE HYGEIA CLOSED TRANSFER SYSTEM UNIT

It is essential that the advice on wearing protective clothing is strictly adhered to at all times when handling sheep dip concentrate, when using the CTS dispensing unit and when washing used concentrate containers and the dispensing unit.

When Handling the Concentrate including Dip Replenishment:

Wear suitable protective clothing. Protective clothing consisting of non-lined synthetic rubber gloves (heavy duty gauntlet style PVC or nitrile at least 0.3mm thick), wellington boots, waterproof trousers or leggings and waterproof coat or bib-apron (made of nitrile or PVC) should be worn when handling the veterinary medicinal product. When handling the concentrate use a face shield. Protective clothing should be in good condition.

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 do not inhale the vapour.

Remove and wash heavily contaminated clothing immediately.

When Working with Diluted Dips and Freshly Dipped Sheep

Minimise operator contamination by good dipping facility design – e.g. fit splash boards where operators stand. The product should only be used in a well ventilated area, preferably outdoors. Avoid use in still-air conditions. Wear suitable protective clothing.

Wash hands, face and exposed skin after a break in dipping and at the end of the day. Accidental splashes should be washed off immediately.

Do not smoke, drink or eat during dipping.

Remove and wash heavily contaminated clothing immediately.

Protective clothing should be washed each day after dipping operations to prevent build up of chemicals.

Wash all equipment after use.

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.

Wear recommended gloves. If the sheep are wet, wear waterproof trousers and coat.

Wash hands and exposed skin after working with recently dipped sheep.

Medical Advice to Users and Doctor:

Diazinon (Dimpylate) is an organophosphorus compound. Do not use if under medical advice not to work with such compounds. If you have felt unwell after using a product containing an organophosphorus compound, you should consult your doctor before working with this product.

Wash all accidental spillages of the concentrate off the skin immediately. Cases of heavy contamination should be treated as an emergency and the patient taken straight to hospital after removing contaminated clothing and rinsing with water areas of skin that came in contact with sheep dip and show the label to the physician.

The symptoms of mild poisoning are a feeling of exhaustion and weakness that may be accompanied by cramp-like abdominal pains, diarrhoea, excessive sweating, constricted pupils and salivation to up to 24 hours after exposure. Severe poisoning can cause general muscle twitching and convulsions.

Doctors can obtain advice on clinical management from the Poisons Information Centre, Beaumont Hospital, Dublin. All cases of organophosphorus poisoning must be treated in hospital.

Special precautions for the protection of the environment:
Dangerous to fish and other aquatic life. Harmful to game, wild and domestic birds and mammals.

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.

See section 5.5.

3.6 Adverse events

Sheep

Undetermined frequency (cannot be estimated from the available data):	Lameness[1]

[1] Post dipping lameness caused by bacterial build up may occur when the sheep are dipped in dirty wash, or wash that has been allowed to stand over-night. See also section 3.4.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or the national competent authority via the national reporting system. See the label for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy and lactation:

Can be used during pregnancy and lactation.

3.8 Interaction with other medicinal products and other forms of interaction

Do not mix with or use with any other dip. Do not combine with copper fungicides. Not to be used with neuroleptic phenothiazine derivatives. Organophosphorous compounds increase the toxicity of these compounds.
As this is an organophosphorous sheep dip, an interval of at least 14 days should elapse between dipping and dosing with any drench, etc., containing an organophosphorous compound.

3.9 Administration routes and dosage

Dipping.
Animals are treated by total immersion in the dip bath.
The veterinary medicinal product must only be dispensed using Hygeia Closed Transfer System (CTS) unit. The unit must be calibrated prior to dispensing into the dip tank. Read the instructions before using the CTS unit.

To prepare the bath:

Measure the required volume of cold water into the bath. Then add the Dip by following the instructions provided with the dispensing kit for fitting it to the container of dip concentrate and for dispensing the dip concentrate safely to the bath in the proportion of –

2.25 litres (0.5 gallon) of dip concentrate [i.e. 9 x 250ml deliveries from the dispensing pump] to 900 litres (200 gallons) of water, equivalent to 250ppm of Diazinon (Dimpylate).

Stir the bath thoroughly from end to end before commencing dipping and dip on the day the bath is prepared.

To dip the sheep:

Immerse the sheep in the bath for a minimum of one minute. Keep the sheep moving forward and crutch the head under at least once. Care should be taken to see that they do not swallow or inhale the wash.

Dip baths of 2250 litres or less must be replenished every 36 sheep. Dip baths over 2250 litres are replenished every 90 sheep. Replenish, as the levels fall, as directed hereunder. This combined with a clean bath, will give best results. If this recommendation is not observed, sheep passing through the bath at a low dip level (or a foul bath) will not be as effectively treated or protected as those passed through earlier.

To replenish the bath:

a) Baths less than 2250 litres (500 gallons): after every 36 sheep dipped, add 1 litre [i.e. 4 x 250ml deliveries from the dispensing pump] into the dip tank and sufficient water to restore the bath to its original volume.
b) Baths greater than 2250 litres (500 gallons): after every 90 sheep dipped, add 2.5 litres [i.e. 10 x 250ml deliveries from the dispensing pump] into the dip and sufficient water to restore the bath to its original volume.

When a bath becomes foul, always empty it and refill with fresh dip.

For the purposes of the control of sheep scab, sheep must be totally immersed in a bath and all parts of the sheep except the heads and ears must remain immersed for not less than one minute.

Plunge the head under at least twice, allowing time to breathe between plunges.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

Diazinon (Dimpylate) is an organophosphorous compound with cholinergic activity, which in excessive doses stimulates the parasympathetic nervous system. Signs of overdose in animals are abdominal pain, diarrhoea, salivation, muscular tremors and constriction of the pupils. Death may occur from respiratory failure.

Emergency procedures/antidotes:
Veterinary advice should be sought. Atropine sulphate is the antidote. If necessary injections may be repeated every 30 minutes.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 Withdrawal periods

Meat and offal: 35 days.

Not authorised for use in lactating ewes producing milk for human consumption.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QP53AF03

4.2 Pharmacodynamics

Diazinon (Dimpylate) is a non-systemic insecticide with some acaricidal action Diazinon (Dimpylate) acts as an irreversible inhibitor of the enzyme cholinesterase. It irreversibly phosphorylates the esterase site of cholinesterase resulting in an increase in acetylcholine.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

It is compatible with most pesticides but should not be combined with copper fungicides.

5.2 Shelf life

Shelf-life of the veterinary medicinal product as packaged for sale: 2 years.

5.3 Special precautions for storage

Do not store above 25°C.
Store in original container tightly closed, in a safe place under lock and key. Keep in a store designated for the storage of approved pesticide.

5.4 Nature and composition of immediate packaging

Fluorinated HDPE bottles with HDPE cap. The cap includes a socket to connect to the CTS unit and a tamper evident tab.

Pack sizes: 2.27 litres (½ gallon), 2.5 litres, 4.54 litres (1 gallon) and 5 litres.

Not all pack sizes may be marketed.

5.5 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products

Medicines should not be disposed of via wastewater or household waste.

The veterinary medicinal product should not enter water courses as this veterinary medicinal product is dangerous to fish and other aquatic life.

Empty containers should not be re-used. Wash out thoroughly and place rinsings into the dip bath. Dispose of containers by approved means. Store well away from children, animals, feedstuffs and food.

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. 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) making sure that it cannot enter rivers, streams or lakes by run-off. Remove livestock from the land before spreading. Alternatively, a reputable waste disposal contractor should dispose of the spent dip.

When the CTS dispensing unit requires disposal, ensure the system is thoroughly rinsed out according to the instructions provided with the unit. Dispose of the CTS unit in accordance with the guidelines from your local waste regulation authority.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Hygeia Chemicals Limited

7. MARKETING AUTHORISATION NUMBER(S)

VPA10203/001/001

8. DATE OF FIRST AUTHORISATION

01/10/1989

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

27/05/2026

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).