

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF VETERINARY MEDICINAL PRODUCT

Gold Fleece Sheep Dip, 608 mg/ml Concentrate for Dip Emulsion

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Substance

Dimpylate (Diazinon) 608 mg/ml

Excipient(s)

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Concentrate for Dip Emulsion.
A clear yellow-coloured liquid.

4. CLINICAL PARTICULARS

4.1 Target Species

Sheep

4.2 Indications for Use, Specifying the Target Species

Sheep: For the prevention and treatment of Blowfly Strike, Ticks, Keds, Lice and Scab infestations.

4.3 Contraindications

None

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.

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. 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.

4.5 Special Precautions for Use

- i. Special precautions for use in animals

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 days dipping or earlier if it becomes very dirty during the day's dipping.

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.

- ii. Special precautions to be taken by the person administering the veterinary medicinal product

For external use only.

One pair of gloves, one laminated dispensing kit instruction card and one laminated sheep dipping safety card are supplied with each container of Gold Fleece Sheep Dip.

The dip concentrate container is fitted with a sealed closure incorporating a male inlet Quick Acting Shut-off coupling (QASC), a female outlet QASC and a draw tube that extends from beneath the outlet QASC to the marked corner of the container. When the container is fitted correctly into the dispensing kit, the tilt mechanism allows withdrawal of the maximum amount of dip concentrate from the container. **The dip concentrate in the container must be dispensed directly into the dip tank only by using the Gold Fleece Sheep Dip Dispensing Kit.** Follow the instructions provided with the dispensing kit for fitting it onto the container and for dispensing the dip concentrate safely.

A re-usable dispensing kit must be purchased in order to use Gold Fleece Sheep dip. Each kit must contain the following components:

- 1x dispensing gun with tubing and 2x connectors (1x male and 1x female) attached,
- 1x dispensing base-plate plus 1x dispensing tube with 1x female connector attached and 1x rinsing tube with 1x male connector and 1x non-return valve attached,
- 1x laminated card, bearing instructions for the correct use of the dispensing kit.

The product must be dispensed only by use of this kit, in accordance with the instructions on the

dispensing kit laminated instruction card. If part-used containers of the product are to be kept for future use, the dispensing kit must be removed, washed and stored as per the instructions, and the original cap must be replaced securely on the product container. The dispensing kit must not be used for any other purpose.

The instructions for use of the dispensing kit read as follows:-

Gold Fleece Sheep Dip concentrate must be dispensed only by using this kit. Read the directions for use printed on the product container before using this kit. It is essential that the advice on wearing protective clothing is strictly adhered to at all times when handling new or part-used containers of sheep dip concentrate, when using the dispensing kit and when washing used concentrate containers and the dispensing kit. This kit is re-usable. It should not be used for any other purpose. It should be washed and stored as directed on the instruction card.

DISPENSING DIP PRODUCT

i. Preparation for dipping:

Place the dip concentrate container into the cage on the base-plate so that the coloured corner of the container label is aligned with the coloured corner of the base-plate. This will tilt the container to allow withdrawal of the maximum amount of dip concentrate. Place the dispensing base-plate on level ground at the edge of the dip tank and feed the dispensing hose through the hole in the base-plate so that the hose hangs down into the dip tank. Where splash-boards are fitted the base-plate should be sited so that the dispensing hose is fed through an existing gap in the barrier. For extra security the base-plate can be attached to a solid object near to the edge of the dip tank using twine or wire threaded through the cage at the rear of the base plate.

ii. Initial fill of dip concentrate into dip bath (see Fig. A):

Connect gun inlet hose (2) to container outlet valve (1) and connect gun outlet (3) to dispensing hose (5). Carefully pump the trigger of the gun until the gun reservoir and outlet tubes are full of product. Then dispense the required number of 60 ml volumes of dip concentrate for initial charging of the dip tank (see container label for details). **The dispensing gun is fixed to deliver 60 ml only and is sealed for safety reasons. It must not be disassembled.** When filling the gun reservoir, to ensure accuracy, it is important to wait until the plunger has returned completely before dispensing the dip concentrate. It is recommended that the operator keeps a tally of the number of volumes dispensed. After every ten x 60 ml dispensings, using a dry gloved finger, press down on the top of container inlet valve (4) for a few seconds (see Fig. B). This is to allow air to enter the container to relieve any negative pressure.

iii. Replenishment of dip bath with product:

(see Figures A & B)

Replenishment with one 60 ml delivery of concentrate treats 12 sheep.

Baths less than 2250 litres (500 gallons) must be replenished after every 36 sheep dipped (3x60 ml deliveries from the dispensing gun) and the bath must be filled with water to its original level.

Baths of 2250 litres (500 gallons) or more **must be** replenished after every 96 sheep dipped (8x60 ml deliveries from the dispensing gun) and the bath must be filled with water to its original level.

Approaching the end of the days dipping, when replenishing the dip bath for the final time, carry out the first 1x60 ml delivery for a bath less than 2250 litres (or the first 6x60 ml deliveries for a bath greater than 2250 litres) and allow the gun to refill by releasing the trigger. Then disconnect gun inlet hose (2) from container outlet valve (1) and connect gun inlet hose (2) to hose (6) ensuring that the non-return valve (7) on the end of the hose is secured to the clip (8) on the carrying handle (see Fig. C). Now pump the gun two more times and the final 120 ml of dip concentrate will be delivered into the dip bath. Replace transit cap onto the part used container. **Now follow instructions on how to wash and store the dispensing kit (see 'Washing Instructions')**.

iv. To change containers during dipping: If a container is emptied during dipping disconnect gun inlet hose (2) from empty container outlet valve (1). Immediately re-connect to a new container and carefully pump the trigger of the gun until the reservoir is full. When disconnected, **do not** try to operate the delivery gun until the correct connections (step ii) have been made. Store the empty container safely until the end of the day's dipping. **Do not rinse empty containers until the end of the day's dipping (see 'Washing Instructions'). This is to avoid the possibility of the introduction of water into part-filled dip concentrate containers. Even very small amounts of water can affect the long-term stability of the dip concentrate.**

WASHING/CLEANING GUN RESERVOIR, HOSE AND EMPTY CONTAINERS

i. At the end of a day's dipping you **must** wash all empty containers to remove residual dip concentrate prior to disposal. The washings **must** be disposed of into the dip tank. Place the empty dip concentrate container into the cage on the base-plate so that the coloured corner of the container label is aligned with the coloured corner of the base-plate exactly as in step (i) of 'Dispensing Dip product' instructions.

ii. To wash out the product container when it is empty (see Fig. D): Disconnect the gun outlet hose (3) from the dispensing hose (5). Connect the gun outlet hose (3) to the container inlet valve (4) and connect gun inlet hose (2) to hose (6). Then immerse the non-return valve (7) in a bucket containing at least 5 litres of clean water. Pump 3 x 60 ml (180 ml) of water into the container and shake the container to rinse it of any remaining dip concentrate.

iii. To empty the product container of rinse water (see Fig. E): Disconnect the gun outlet hose (3) from the container inlet valve (4). Connect the gun outlet hose (3) to the dispensing hose (5). Disconnect the gun inlet hose (2) from the hose (6). Connect the gun inlet hose (2) to the container outlet valve (1). Pump the gun repeatedly to remove all of the rinsings from the container into the dip-tank.

Repeat the rinsing and emptying processes two more times to ensure that the product container is empty of all traces of product before disposing of the container.

iv. To wash out gun reservoir and hose:

Having rinsed the empty containers, or at the end of a day's dipping when no dip container

has been emptied, you **must** then rinse out the gun reservoir and hose to maintain it in working order. Before following the washing procedure, if a part-filled container remains you **must** remove it from the cage and store it safely with the cap replaced. If not already in place, connect gun inlet hose (2) to hose (6). Ensure that gun outlet hose (3) is connected to dispensing hose (5). Then immerse the non-return valve (7) in a bucket containing at least 5 litres of clean water. Pump at least 10 x 60 ml through the gun and the tubing into the dip tank to ensure that the gun reservoir and hosepipes are clear of dip concentrate.

v. To clear gun reservoir and hose of water:

Remove the non-return valve (7) from the water and secure it in clip (8) on the kit handle. Pump the dispensing gun until the gun reservoir and hose are completely clear of water. Disconnect gun outlet hose (3) from dispensing hose (5) and gun inlet hose (2) from hose (6). Rinse the outside of the dispensing hose and valves (2) and (3) by immersing in a bucket of clean water, then agitate and rinse all valves. Dispose of the rinse water in the dip tank. Rinse valves (5) and (6) by spraying with water so that the rinsings drain into the dip-tank, taking care to avoid splashing yourself or others. Repeat this process two more times. Then store the dispensing kit in the original carton, in a dry place below 25°C as follows: Connect gun outlet hose (3) to dispensing hose (5) and connect gun inlet hose (2) to hose (6). Then secure the non-return valve (7) in clip (8) on the kit handle. This allows the air to dry the gun reservoir and hose system. A part-used container can be stored (with its cap replaced) in the base-plate cage.

vi. Disposal:

The dispensing kit has been shown in tests to withstand 5 years of simulated use. If you do need to dispose of the kit, rinse the gun and hoses thoroughly as in steps (iv) & (v). Dispose of the dispensing kit in accordance with guidance from your local waste regulation authority.

Before Dipping

Dimpylate (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:

- Do not use concentrate in an enclosed area and avoid breathing the vapour. Dipping should be carried out in a well-ventilated area, preferably outdoors.
- Always use the Gold Fleece dispensing kit provided when dispensing concentrate.
- 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 dispensing kit and dipping equipment in accordance with the instructions at the beginning of this section. 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.
- If you feel unwell after using this product consult your doctor and show your doctor this 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 this label with you.

- 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 to medical practitioners: Advice on clinical management is available from the National Poisons Information Service. Further information for health professionals is contained in MS17 entitled “Medical aspects of work related exposure to organophosphates” and is available from HSE books on tel: 01787 881165 or fax 01787 313995.

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 4.5.i.

4.7 Use during pregnancy, lactation or lay

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

There have been no reported complications in pregnancy or lactation.

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

4.8 Interaction with other medicinal products and other forms of interaction

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:

Measure the required volume of cold soft water into the bath. Fit the Dispensing kit (available from your Gold Fleece supplier) to the dual valved lid of the container as described in section 4.5 above.

Dispense the required amount of product into the dip tank via the dispensing kit in the proportion of 600ml Gold Fleece to 900 litres (200 gallons) of water (i.e dispense 10 x 60ml amounts of dip concentrate into the dip tank – see section 4.5 above). Stir the bath thoroughly from end to end before commencing dipping and dip on the day the dip is prepared.

To replenish the bath:

Baths of less than 2250 litres (500 gallons).

Add 180 ml of dip after every 36 sheep dipped and restore the bath with water to its original Volume (i.e dispense 3 x 60ml amounts of dip concentrate into the dip tank – see section 4.5 above).

Baths of 2250 litres (500 gallons) or more.

Add 480 ml of dip after every 96 sheep dipped and sufficient water to restore the bath to its original volume (i.e dispense 8 x 60ml amounts of dip concentrate into the dip tank see section 4.5 above). When a bath becomes foul, however, always empty it and refill with fresh dip. Dispose of all wash remaining at the end of a day's dipping.

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. You should then empty, clean and recharge the bath with fresh dip wash.

Dipping: Sheep must be totally immersed in a sheep bath and all parts of the sheep except the head and ears, must remain immersed for not less than one minute. Keep the sheep moving in the bath and plunge the head under at least once. Never hold the head down or the sheep will be liable to swallow or inhale some of the wash.

Control of Ticks: Ewes: 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.

Not to be mixed with any other dip.

4.9 Overdose

Care should be taken not to overdose.

Overdosing may invalidate the stated meat withholding times as in 4.11 below.

4.10 Withdrawal Period(s)

Sheep (meat & offal): 49 days.

Not to be used on animals producing milk for human consumption.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Ectoparasiticides for topical use, organophosphorus compounds.

ATCvet code: QP53AF03

5.1 Pharmacodynamic properties

Dimpylate (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.

Used as a sheep dip at a concentration of 0.025%, Dimpylate (Diazinon) is active locally in the skin and wool. Owing to their lipid solubility, they are rapidly absorbed into the oily secretions on wool and the skin surface and persists at concentrations effective against mites, lice and blowfly for at least 60 days.

5.2 Pharmacokinetic properties

Parenterally absorbed organophosphates are metabolised by hydrolysis and oxidation and excreted mainly via the urine.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Emulsogen IT
Paraffin, light liquid
Epoxidised Soya Bean Oil

6.2 Major incompatibilities

Incompatible with copper sulphate and its solutions.

6.3 Shelf Life

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

6.4 Special Precautions for Storage

Do not store above 25°C.

Store in original container, tightly closed, in a safe place.

Not to be mixed with any other dip.

In freezing conditions, the container must be shaken vigorously before use.

Wash out container and dispose of safely.

Keep away from food, drink and animal feeding stuffs.

6.5 Nature and composition of immediate packaging

A brown coloured emulsifiable concentrate packed in a rectangular 5 litre tin container. The dip concentrate container is fitted with a non-removable sealed closure incorporating a male inlet Quick Acting Shut-off coupling (QASC), a female outlet QASC and a draw tube that extends from beneath the outlet QASC to the marked corner of the container. When the container is fitted correctly into the dispensing kit, the tilt mechanism allows withdrawal of the maximum amount of dip concentrate from the container. **The dip concentrate in the container must be dispensed directly into the dip tank only by using the Gold Fleece Sheep Dip Dispensing Kit.**

6.6 Special Precautions for the disposal of unused veterinary medicinal product or waste material, if any

Dangerous to fish and other aquatic life. Do not contaminate surface waters. Harmful to game, wild and domestic birds and mammals. Do not allow access to dilute dip.

It is an offence to permit any poisonous, noxious or polluting matter to enter any river, stream or watercourse.

Any unwanted product should be disposed of by a licensed waste disposal contractor.

Empty containers should be washed out three times, as directed in the washing instructions provided with the Dispensing Kit and the rinsings placed into the dip bath. Because the container is a closed, sealed system, it **must** be punctured before crushing. The dispensing kit has been shown in tests to withstand 5 years of simulated use. If you do need to dispose of the kit, rinse the gun and hoses thoroughly as directed in the washing instructions provided with the Dispensing Kit. Dispose of rinsed containers and the dispensing kit in accordance with any guidance from an appropriate waste regulation authority.

To dispose of used sheep dip an authorisation under the Groundwater Regulations 1998 is required. To apply for an authorisation contact the Environment Agency (EA) or the Scottish Environment Protection Agency (SEPA) or the Environment and Heritage Service of the

Department of the Environment for Northern Ireland (EHS/DENI). Alternatively spent dip wash should be disposed of by a licensed waste disposal contractor.

7. MARKETING AUTHORISATION HOLDER

Bimeda Animal Health Limited
2 / 3 / 4 Airton Close
Tallaght
Dublin 24
Ireland

8. MARKETING AUTHORISATION NUMBER

Vm 50146/4031

9. DATE OF FIRST AUTHORISATION

01 October 1996

10. DATE OF REVISION OF TEXT

November 2021

Approved 24 November 2021

A handwritten signature in black ink, appearing to read "J. Hunter.", is positioned below the approval date.