1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Gold Fleece Sheep Dip 600 mg/g Concentrate for Dip Solution

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance:

Dimpylate (Diazinon Stabilised Technical) 600 mg/g.

Excipients:

Qualitative composition of excipients and other constituents
Emulsogen IT
HAN 8572
Epoxidised soya bean oil

A clear yellow coloured liquid.

3. CLINICAL INFORMATION

3.1 Target species

Sheep.

3.2 Indications for use for each target species

For the prevention and treatment of blowfly strike, keds, lice and scab infestations.

3.3 Contraindications

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 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.

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 day's dipping.

3.5 Special precautions for use

Special precautions for safe use in the target species:
See also 3.12.

One pair of gloves and one laminated dispensing kit instruction card is supplied with each container of the veterinary medicinal product.
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 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 the veterinary medicinal product 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 veterinary medicinal 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 the use of the dispensing kit read as follows:

The veterinary medicinal product 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 to a solid object 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 dispensing's, 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 the 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 the 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 the 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). Disconnect the gun outlet hose (3) to the container inlet valve (4) and connect gun inlet hose (2) to hose (6). Then immerse in 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 and 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 out 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) and (v). Dispose of the dispensing kit in accordance with guidance from your local waste regulation authority.

Special precautions to be taken by the person administering the veterinary medicinal product to 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. People with known hypersensitivity to diazinon should avoid contact with the veterinary medicinal product.

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

Keep children well away from 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.

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 in Section 3.5. 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 under **Medical Advice to Users**. Wash or destroy heavily contaminated clothes immediately.

If you feel unwell after using this veterinary medicinal product seek medical advice immediately and show the package leaflet or the label to the physician. 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.

A. When handling concentrate including dip replenishment:

i. Do not use in an enclosed area and avoid inhaling the vapour.
ii. Wear non-lined, synthetic rubber gloves (heavy-duty gauntlet style nitrile at least 300 mm in length and 0.5 mm thick), wellington boots, waterproof (made of nitrile or PVC) trousers or leggings and coat or bib-apron and a face shield when handling the concentrate.
iii. Wash splashes of the dip concentrate from the skin and eyes and from protective clothing and equipment immediately.
iv. Remove heavily contaminated clothing immediately and wash or destroy.

B. When working with diluted dips and freshly dipped sheep:

i. Dipping should only be carried out in a well-ventilated area, preferably outdoors.
ii. Wear non-lined, synthetic rubber gloves (heavy-duty gauntlet style nitrile at least 300 mm in length and 0.5 mm thick), wellington boots, waterproof (made of nitrile or PVC) trousers or leggings and coat or bib-apron.
iii. Accidental splashes on exposed skin should be washed off immediately. Wash hands, face and exposed skin immediately after leaving the work area, e.g. after dipping or for meal breaks.
iv. Do not smoke, drink or eat during dipping without first withdrawing from the work area, removing protective clothing and washing hands, face and exposed skin.
v. Remove heavily contaminated clothing immediately and wash or destroy.
vi. Check and replace any worn or damaged items of protective clothing.
Wash measuring and dipping equipment after use. Protective clothing should be washed each day after dipping operations to prevent build-up of chemicals in the materials.

C. 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 and smoking.

D. Medical advice to users:

If you have breathing problems, or if you have felt persistently unwell after using a product containing an organophosphorus compound, you should consult your doctor before working with the product.

Treat any cases of heavy contamination as an emergency. Take the patient straight to hospital after removing contaminated clothing and rinsing with water areas of skin which come into contact with sheep dip. Tell the doctor you have been dipping with the veterinary medicinal product which contains Diazinon.

E. Medical advice to doctors:

The symptoms of mild poisoning from organophosphorus compounds are a feeling of exhaustion and weakness, which may be accompanied by cramp-like abdominal pains, diarrhoea, excessive sweating, constricted pupils and salivation up to 24 hours after exposure. Severe poisoning causes generalised muscle twitching and convulsions.

Doctors can obtain advice on clinical management from the National Poisons Information Centre, Beaumont Hospital, Dublin.

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 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.

See section 5.5.

Other precautions:
Harmful to poultry. Keep birds away from the veterinary medicinal product and the prepared bath.

3.6 Adverse events

Sheep:

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

[1]Post dipping lameness may occur when the sheep are dipped in dirty wash, or wash that has been allowed to stand overnight. 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:
There have been no reported complications in pregnancy or lactation.
If dipping pregnant sheep, it is essential they should be gently lowered into the bath and assisted out.

3.8 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.

3.9 Administration routes and dosage

Dipping.

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 3.5 above. Dispense the required amount of
product into the dip tank via the dispensing kit in the proportion of 600 ml dip concentrate to 900 Litres (200 gallons) of water (i.e. dispense 10 x 60 ml amounts of dip concentrate into the dip tank – see section 3.5 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:

Mix the dip concentrate into the water after the initial fill and after each replenishment by stirring thoroughly with a metal rod, preferably with a paddle attachment. Avoid using wooden dunking poles as these may absorb dip and result in prolonged exposure after dipping.

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 60 ml amounts of dip concentrate into the dip tank – see section 3.5 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 60 ml amounts of dip concentrate into the dip tank – see section 3.5 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.

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 its head under at least once. Never hold the head down or the sheep will be liable to swallow or inhale some of the wash.

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 day's dipping. Do not dip more than one sheep for each 2 litres of dip-wash prepared before emptying and preparing fresh dip-wash.

Dispose of all wash remaining at the end of day's dipping.

Sheep Scab - Its Cure and Prevention:

For the purposes of dipping against sheep scab, sheep must be totally immersed in a sheep bath of an approved sheep dip, and all parts of the sheep except the head and ears must remain immersed in the bath for a period which shall in no case be less than one minute.

Plunge the head under at least twice.

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

Care should be taken not to overdose.
Overdosing may invalidate the stated meat withholding times as in 3.12 below.

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.

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

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QP53AF03

4.2 Pharmacodynamics

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.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Not to be mixed with any other dip.
Incompatible with copper sulphate and its solutions.

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 the original container.
Keep the container tightly closed, in a safe place.

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.

5.4 Nature and composition of immediate packaging

3 litres of a clear yellow coloured emulsifiable concentrate packed in a 5 litre tin container. The dip concentrate is fitted with a sealed closure incorporating a male inlet Quick Acting Shut-off coupling (QASC), a female outlet QASC and a draw tube inside the container that extends from beneath the outlet QASC to the marked corner of the container. When the container is fitted correctly into the basket of the dispensing kit, the tilt mechanism allows withdrawal of the maximum amount of dip concentrate from the container.

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.

This veterinary medicinal product should not enter water courses as this veterinary medicinal product is extremely dangerous for fish and other aquatic organisms.

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. Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

Empty containers should not be re-used for any other purpose. Rinse the empty container three times as directed in the washing instructions provided for the dispensing kit and dispose of all rinsings in the dip tank. Because the container is a closed sealed system, it must be punctured before crushing. Dispose of containers by approved means. Store well away from children, food, animals and animal-foodstuffs.

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). 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 dip wash should be disposed of by a reputable waste contractor.

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

Bimeda Animal Health Limited

7. MARKETING AUTHORISATION NUMBER(S)

VPA22033/023/001

8. DATE OF FIRST AUTHORISATION

01/10/1989

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

24/04/2026

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).