

SUMMARY OF PRODUCT CHARACTERISTICS

1. Name of Veterinary Medicinal Product

Paracide 62 %w/v, Concentrate for dip emulsion.

2. Name and proportion of each Active Substance

Dimpylate (Diazinon) 62% w/v

Name and proportion of each Excipient if knowledge of the Excipient is needed for Safety reasons

Propylene oxide 1.03% w/v

3. Pharmaceutical Form

Concentrate for Dip emulsion

4. Clinical Particulars

4.1 Target species

Sheep

4.2 Indications for use, specifying the target species

For the control of sheep scab, blowfly, ticks, keds and lice on sheep.

4.3 Contra-indications

Do not use the product undiluted.

Do not retain the dip wash for a second day's dipping.

4.4 Special warnings for each target species

Efficacy has not been demonstrated for the use of the product in shower dips or jetting races.

As with all dips, the effectiveness of the uptake of insecticide may be reduced if the bath is overloaded with organic material. It is recommended that dip baths containing this product be discarded when the bath becomes too fouled with droppings, etc.

The dipwash in baths of 250 gallons (1050 litres) or less, containing this product should be discarded after the passage of approximately 400 sheep through the bath. The dipwash in baths larger than 250 gallons (1050 litres) should be discarded after the passage of 1 sheep for every 2 litres (2 sheep to 1 gallon) of the initial bath volume.

4.5 Special Precautions for Use

(i) Special precautions for use in animals

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

The dip should be freshly made and only used on the day of preparation. Do not retain the dip wash for a second day's dipping. Prepare the bath carefully and dip following the detailed instructions. Ensure the bath and water are clean before starting to dip. This product does not contain a bacteriostat and 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.

Avoid extremes of heat and cold as well as thunder and wet weather. As far as possible, do not carry out dipping in the rain or when the fleece is wet. Choose a fine day free from impending rain. In winter, do not dip sheep in very frosty weather and, if available, carry out dipping in a well ventilated sheltered yard.

Dipping in the early morning is best so that the sheep can dry before the evening. This is especially advised where dipping in hot weather is unavoidable because the temperature is cooler up to 9 am.

Do not dip sheep when they are tired, heated, thirsty, suffering from scour or wounds or otherwise out of condition, nor when full of food. Keep the sheep off food and rest them quietly near the bath for a few hours both before and after dipping, making sure they are not crowded together.

Drain them well in a bare place and do not return them to pasture until they have ceased dripping.

Rams and fat sheep are susceptible to immersion shock, therefore never dip them on a sultry day and always dip them separately about the middle of the general dipping, carefully assisting them through the bath.

Care must be taken to avoid sheep inhaling or swallowing the wash.

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

(ii) **Special precautions to be taken by the person administering the veterinary medicinal product**

PREPARATION FOR DIPPING:

Diazinon is an ORGANOPHOSPHORUS compound. DO NOT USE if under medical advice not to work with such compounds.

Only use in a dip bath that is well designed and hazard free. Check that all those involved are adequately trained and competent.

Keep children well away from all dipping operations.

Make sure that everyone involved in dipping operations has the recommended protective clothing and **insist** that they wear it.

Ensure you have spare protective clothing available in case any items become damaged (see below for '**PROTECTIVE CLOTHING**').

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

PROTECTIVE CLOTHING:

The recommended protective clothing is:

- **Face shield (when handling the 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 – 0.5mm thick and at least 300mm long)**
- **Waterproof leggings/trousers (PVC or nitrile to be worn outside your boots)**
- **Wellington boots.**

DURING DIPPING:

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

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.

Immediately remove heavily contaminated clothes and wash contaminated areas of skin – see further instructions below under '**Medical advice to users**' and '**Disposal**'.

If you need to handle the sheep in the weeks following dipping wear protective clothing because dip residues remain on the fleece.

MEDICAL ADVICE TO USERS:

If you have previously felt unwell after using a product containing an organophosphorus compound, consult your doctor before working with this product and show your doctor this label.

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 the skin that came into contact with the sheep dip. If sheep dip has been swallowed go straight to hospital and take the product label with you.

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 bronchorrhea. 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.

AFTER DIPPING:

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

Do not house freshly dipped sheep in an enclosed building.

In the 3 month period after dipping you are advised not to shear sheep.

(iii) Other precautions

For external use only.

If you sell the sheep you should tell the new owner when the animals were last dipped. If you take sheep to market it is good practice to ask the auctioneer to record (and pass on the new owner) the date your animals were last dipped particularly if they were dipped during the last 3 months.

Never re-use concentrate containers.

4.6 Adverse reactions (frequency and seriousness)

Immersion shock has been reported, particularly in rams and fat sheep. See section 4.5. Post dipping lameness caused by bacterial build up in the bath has also been described if the bath is not cleaned and replaced according to instructions.

4.7 Use during pregnancy, lactation or lay

Pregnant sheep may become stressed if dipped. 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

This dip must not be used in conjunction with any other dip and must be diluted with water in the recommended proportions.

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

4.9 Amounts to be administered and administration route

This product is supplied in containers that are part of a Closed Transfer System and should only be dispensed through the Animax Manual Pump. Do not attempt to remove the container fittings under any circumstances. To do so would invalidate the legality of the dipping operation, remove any product guarantee and be a breach of health and safety practice. The container is fitted with a tamper evident insert that cannot be removed without extreme force. This product should only be used at an ambient temperature of between 5°C and 25°C. If used outside these temperatures inaccurate dosing will occur. Before dipping commences, ensure that the dip bath is cleaned and prepare a fresh solution as described below.

INITIAL BATH: Dilute at a rate of one part of dip concentrate to 1500 parts of clean water.

Paracide 62 Initial Dilution at a rate of 1 litre of Paracide 62 to 1500 litres of clean water. If your dip bath is calibrated in gallons you get 4.55 litres in 1 gallon (e.g. 22 gal = 100L)				
BATH VOLUME IN LITRES	600	1200	2400	4800
VOLUME OF PARACIDE 62 TO ADD	400 ml	800 ml	1.60 litres	3.20 litres

ALL REPLENISHMENTS: Dilute at the rate of 1 part of dip concentrate to 1000 parts of clean water. Replenish the bath after the passage of every 20 sheep through the bath according to the table below. If the drain back facilities are such that the bath volume is not depleted to the minimum volume indicated in the table after the passage of 20 sheep, it is necessary to replenish the bath with 50 ml of dip concentrate together with the amount of water required to return the bath to the original volume.

Paracide 62 topping up system. Top up after 20 sheep at a rate of 1 litres of Paracide 62 to 1000 litres of clean water. If the volume of the dip bath drops by less than 50 litres after 20 sheep still add 50 ml of Paracide 62 and top up with water to the original level.						
BATH LEVEL DROP IN LITRES	50	75	100	150	200	250
VOLUME OF PARACIDE 62 TO ADD	50 ml	75 ml	100 ml	150 ml	200 ml	250 ml

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

Diazinon is an organophosphorus compound with cholinergic activity, which in excessive doses stimulates the parasympathetic nervous system.

The symptoms of overdosing in animals are abdominal pain, diarrhoea, salivation, muscular tremors and constriction of the pupils. Death may occur from respiratory failure.

Should toxicity symptoms appear, atropine sulphate is antidotal and should be given either subcutaneously or intramuscularly at 0.1 - 0.2 mg/kg bodyweight until signs of atropinisation appear, i.e. decreased salivation, dilation of pupils and tachycardia. Give additional doses if necessary as often as every 10 minutes. Close surveillance and a mild degree of atropinisation should be maintained for 25 - 48 hours or possibly longer. In severe cases, if pralodoxime chloride is available, give intravenously at 20 mg/kg bodyweight and repeat after one hour. In such cases, atropine may be administered concurrently.

4.11 Withdrawal Periods

Meat and offal: 70 days

Do not treat sheep producing milk for human consumption

5. Pharmacological Properties

Pharmacotherapeutic group: Ectoparasitocides for topical use, incl. Insecticides, organophosphorous compounds,
ATCvet code: QP53AF03

5.1 Pharmacodynamic properties

Diazinon is an organophosphate ester with strong insecticidal and acaricidal activities; it exerts its effect by contact and by stomach and respiratory toxicity in ectoparasites.

The mode of action of the compound is by cholinesterase inhibition similar to other organophosphate insecticides.

Diazinon has been used successfully to control both agricultural and veterinary parasites in a variety of formulations, including emulsifiable concentrate, wettable powder, aerosol and dusting powder.

Paracide 62, when used at the recommended initial and replenishment rates will eradicate and provide residual protection against sheep scab, blowfly, ticks, keds and lice on sheep.

5.2 Pharmacokinetic properties

Diazinon is readily metabolised, largely by cleavage of the pyrimidinyl phosphorous ester bond and eliminated predominantly via the urine.

Following plunge dipping as recommended above mean fleece levels of c 3,900 mg/kg (ppm) are deposited in the fleece bound to the lanolin component. These level decline over time to c 700 mg/kg (ppm) at 5 weeks post dipping and 150 mg/Kg (ppm) at 7 - 8 weeks post dipping. There is considerable variation between individual sheep results.

Percutaneous absorption from this depot in wool fat is low.

The compound is relatively stable at normal temperatures and shows some residual activity.

6. Pharmaceutical Particulars

6.1 List of excipients

Propylene oxide
Liquid paraffin
Polysorbate 80
Castor oil, polyoxyl
Sorbitan trioleate

6.2 Major Incompatibilities

Diazinon is incompatible with copper compounds and oxidising agents.

The material is slowly decomposed by water and dilute acids.

Diazinon is incompatible with levamisole.

6.3 Shelf-life

Concentrate – 2 years.

Diluted – 1 day.

The dip wash must be discarded and disposed of safely at the end of the day.

6.4 Special Precautions for Storage

Store in tightly closed original container. Do not store above 25°C.

Keep in a store designed for the storage of approved pesticides.

Store away from food, drink and animal feedstuffs.

6.5 Nature and Contents of immediate packaging

5 and 10 litre steel drums containing a clear pale amber coloured emulsifiable concentrate ectoparasiticide sheep dip for dilution with water. Each drum is sealed with a special non-removable cap that allows the product to be dispensed through a closed transfer (CT) System, the Animax Manual Pump.

6.6 Special Precautions for the Disposal of Unused Veterinary Medicinal Products or Waste Material derived from the use of such products, if appropriate

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

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

Empty containers should be rinsed out according to the instructions supplied with the CT system and the rinsings pumped into the dip bath. This process must be carried out three times. The rinsed containers should be punctured at the dipping site and can then be disposed of 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 or Scottish Environment Protection Agency (SEPA) or the Northern Ireland Environment Agency. Alternatively, spent dip wash should be disposed of by a licensed waste disposal contractor.

7. Marketing Authorisation Holder

Animax Ltd
Shepherds Grove West
Stanton
Bury St Edmunds
Suffolk
IP31 2AR

8. **Marketing Authorisation Number**
Vm 14016/4007
9. **Date of the first authorisation**
Date: 13 August 1985
10. **Date of revision of the text**
Date: April 2015

APPROVED T. NASH 30/04/15