

[Version 9,03/2022]

ANNEX I
SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Ecofleece 100 mg/g Concentrate for dip emulsion for sheep.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance:

Cypermethrin High Cis (80/20) 100 mg/g

Excipients:

Qualitative composition of excipients and other constituents
N-methyl 2 pyrrolidone
N-octyl 2 pyrrolidone
Ethoxylated Castor Oil
Pluronic L31
Rhodafac RS 710

A clear, pale yellow liquid.

3. CLINICAL INFORMATION

3.1 Target species

Sheep.

3.2 Indications for use for each target species

Sheep: for the prevention and treatment of blowfly strike, lice, keds and ticks on sheep by plunge dipping after dilution of the product with water. For the prevention and treatment of sheep scab caused by pyrethroid sensitive mites.

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

Unnecessary use of antiparasitics or use deviating from the instructions given in the SPC may increase the resistance selection pressure and lead to reduced efficacy. The decision to use the product should be based

on confirmation of the parasitic species and burden, or of the risk of infestation based on its epidemiological features, for each individual animal or flock.

The use of this product should take into account local information about susceptibility of the target parasites, where available.

It is recommended to further investigate cases of suspected resistance, using an appropriate diagnostic method.

Confirmed resistance should be reported to the marketing authorisation holder or to the competent authority.

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:

After dipping, sheep should be allowed to stand in a bare open space under shade if possible but never in an enclosed building. For best results sheep should not be dipped soon after shearing but should have at least 3 weeks growth of wool.

Animals should not be dipped when they are heated, tired or thirsty.

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.

When handling concentrate including dip replenishment:

- Do not use in an enclosed area and avoid inhaling vapour.
- Personal protective equipment consisting of 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 should be worn when handling the veterinary medicinal product.
- Wash splashes of the dip concentrate from skin and eyes and from protective clothing and equipment immediately.
- Remove heavily contaminated clothing immediately and wash or destroy.

When working with diluted dips and freshly dipped sheep:

- Dipping should only be carried out in a well ventilated area, preferably outdoors.
- Personal protective equipment consisting of 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 should be worn.
- Accidental splashes on exposed skin should be washed off immediately. Wash hands, face and exposed skin immediately after leaving the work area, removing protective clothing and washing hands, face and exposed skin.
- 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.
- Remove heavily contaminated clothing immediately and wash or destroy.
- 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.

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.
- If you need to handle sheep, wear coveralls and wellington boots. If the sheep are wet, wear waterproof trousers and coat or bib-apron and wellington boots.
- Always wash hands and exposed skin with soap and water after handling sheep or fleece and before eating, drinking and smoking.

Medical advice to users and doctor:

- Please note that the veterinary medicinal product is a non-organophosphorus sheep dip.
- This product contains cypermethrin which is a synthetic pyrethroid. Cypermethrin is a potential skin sensitiser and may induce paraesthesia or tingling effects on exposed areas of human skin.
- Wash all accidental spillages of the concentrate and diluted dip off the skin immediately. If you feel unwell after working with this product consult your doctor and show the label.
- Doctors can obtain advice on clinical management from the National Poisons Information Centre.

Harmful in contact with skin and if swallowed. Irritating to eyes and skin.

3.6 Adverse events

Sheep:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Lameness*
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*Post dipping lameness may occur when sheep are dipped in dirty wash or wash that has been allowed to stand overnight.

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 also the last section of the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy and lactation:

The safety of the veterinary medicinal product has not been established during pregnancy or lactation.

3.8 Interaction with other medicinal products and other forms of interaction

None known.

3.9 Administration routes and dosage

For Blowfly, Keds, Lice and Ticks

Initial Dilution Rate: 1 in 500
Replenishment: 1 in 500

For Sheep Scab

Initial Dilution Rate: 1 in 500

Replenishment:

1 in 500

A single treatment will provide up to 9 weeks control of Blowfly Strike. Occasionally retreatment may be necessary after 4 – 9 weeks depending on the level of challenge, weather conditions and the timing of the first dipping.

Underdosing could result in ineffective use and may favour resistance development.

Do not dilute the product until it is actually required.

GUIDE TO YOUR REQUIREMENTS

The table below shows the amount of dip required to prepare dipping baths of various size and refers to the initial dilution rate of 1 in 500.

Dip required to make up Bath:

Bath Size	220 gall. 1000 litres	350 gall. 1600 litres	400 gall. 1800 litres	440 gall. 2000 litres	500 gall. 2250 litres
Add	2 L	3.2 L	3.6 L	4 L	4.5 L

Estimated dip requirements for your flock:

An estimate of the number of litres required to dip your flock in typical bath sizes is shown below. Top up bath after every 50 sheep (refer to 'Replenishment' section). The first number in the shaded area is an indication of the number of sheep that may be dipped before making up a fresh bath, depending on the capacity of the dipping tank.

Bath Size	220 gall. 1000 litres	350 gall. 1600 litres	400 gall. 1800 litres	440 gall. 2000 litres	500 gall. 2250 litres
Litres Required					
2	50	-	-	-	-
3	300	-	-	-	-
4	550	250	150	50	-
5	-	500	400	300	175
6	600	750	650	550	425
7	850	-	900	800	675

The numbers in **bold** indicate the number of sheep in the flock to be dipped.

The shaded areas on the table indicate where both bath emptying and refilling should take place in line with good dipping practice.

To prepare the bath: Baths should be accurately calibrated. Fill the bath with the required quantity of clean water. Pour the required measured volume of dip directly into the bath to give the required strength. Stir the bath thoroughly from end to end to ensure complete mixing.

Replenishment: Replenish after every 50 sheep dipped. The bath should be topped up to its original volume with water. Then add 20 ml of dip concentrate for each 10 litres of water added.

Dipping: Blowfly, Lice, Keds and Ticks: Immerse the sheep in the bath until the fleece is completely saturated with dip wash. All parts of the sheep except the head and ears must remain immersed for not less than thirty seconds. Plunge the head under at least twice, allowing time to breathe between plunges. To reduce the risk of blowfly strike, control worms and treat all wounds.

Skim off at regular intervals any scum, which may form on the surface of the dipping bath.

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 once.

To prevent fouling of the bath: It is important that the dip bath is emptied and thoroughly cleaned at the end of each day's dipping or earlier if it becomes very dirty during the day's dipping. Dip no more than one sheep for every 2 litres of the initial bath volume before the bath is completely emptied.

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

Tolerance studies at 2.5 times the recommended dosage rate indicated excellent tolerance by the target species.

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

In the case of overdosing, treatment should be symptomatic.

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

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

Meat and offal: 14 days.

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

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QP53AC

4.2 Pharmacodynamics

Cypermethrin is a synthetic pyrethroid insecticide used for both crop protection and to control ectoparasites on livestock.

Cypermethrin is a contact poison, having a rapid paralytic action on insects, preceded by muscular excitation and convulsions. The pyrethroids have sufficient prolonged stability on the animal to have a knockdown and kill effect on insects.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Do not mix with any other veterinary medicinal product.

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.

Protect from light.

Store in original container, tightly closed, in a safe place, under lock and key in a press dedicated to approved pesticides.

Do not store diluted dipwash overnight.

Discard the diluted product after each days dipping.

5.4 Nature and composition of immediate packaging

Multilayered plastic containers with an internal polyamide layer in 1 litre, 2 litre and 5 litre sizes containing a pale yellow, clear, dip concentrate that on addition to water disperses with mixing to form a clear microemulsion. The containers are sealed with a tamper-evident polyethylene screwcap which has a tear-off locking flange.

1 litre plastic container.

2 litre plastic container.

5 litre plastic 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

Dangerous to fish and other aquatic life.

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

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.

The veterinary medicinal product should not enter water courses as cypermethrin is dangerous for fish and other aquatic organisms. Therefore, it is important to ensure that sheep have an area where dip can drip from the fleece and drain back into the bath immediately after dipping and to ensure that sheep do not enter or cross watercourses whilst the fleece is still wet. Do not dip sheep near a watercourse.

Empty containers should not be re-used. Wash out thoroughly and place rinsings into the dip bath.

Dispose of containers by approved means.

Only buy sufficient product for immediate use. Do not dispose of the dip concentrate on the farm. Any undiluted product should be disposed of by a reputable specialist waste disposal contractor.

The spent dip should be disposed of by a reputable waste disposal contractor. If you have a suitable area of land, you may apply not more than 5 m³ of used dip per hectare (450 gallons/acre).

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)

VPA 22033/012/001

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: 11 September 1996

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

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>).