

ANNEX III
LABELLING AND PACKAGE LEAFLET

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE - COMBINED LABEL AND PACKAGE LEAFLET

1L, 2.5L, 5l

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE , IF DIFFERENT

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

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Fly Off 12.5 mg/ml Pour-On Solution for Sheep

3. STATEMENT OF THE ACTIVE SUBSTANCE (S) AND OTHER INGREDIENTS

Containing 12.5 mg/ml cypermethrin

Green S Dye (E142) 0.2 mg/ml

4. PHARMACEUTICAL FORM

Pour-on solution

5. PACKAGE SIZE

1 litre, 2.5 litres or 5 litres

6. INDICATION(S)

For the treatment and control of headflies. For the treatment of tick infestation with a persistent efficacy of 10 weeks (the majority of ticks killed within 3 hours) and treatment of biting lice in sheep. For the prevention and treatment of blowfly strike in sheep

7. CONTRAINDICATIONS

Not to be used in lambs less than one week old.
Avoid treating very young lambs if the weather is unseasonably hot.
For the prevention of blowfly strike; do not administer to animals of less than 12.5 kg bodyweight.

Do not use in case of hypersensitivity to the active substance or to any of the excipients.

8. ADVERSE REACTIONS

If you notice any side effects, even those not already listed in this label or you think that the medicine has not worked, please inform your veterinary surgeon.

9. TARGET SPECIES

Sheep

10. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

On completion of each treatment cycle of the product and before the dosing gun is stored, immediately expel any remaining product in the dosing gun.

To ensure administration of a correct dose, body weight should be determined as accurately as possible; accuracy of the dosing device should be checked.

Administer by means of the recommended applicator gun as follows:

Blowflies:

Prevention of blowfly strike

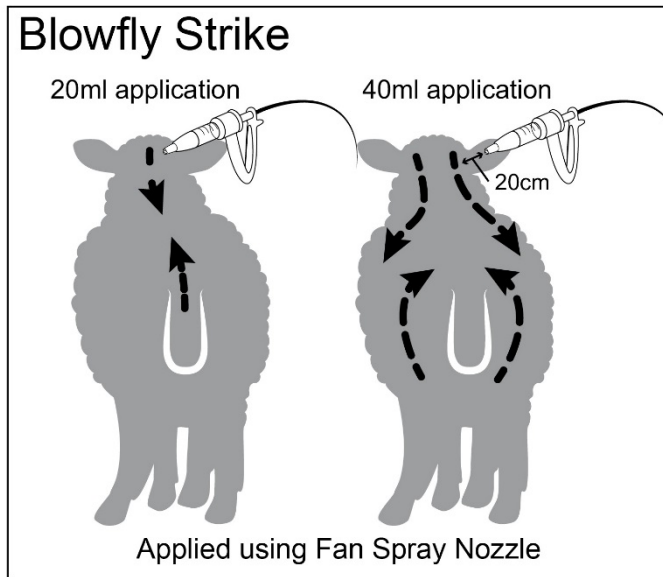
Bodyweight Dose Doses per litre

Up to 25 kg*	20 ml	50
25 to 40 kg	30 ml	33
Over 40 kg	40 ml	25

*Do not administer to animals of less than 12.5 kg bodyweight.
The dose should be limited to a maximum dose of 40 ml per animal.

Apply as a fan-spray to the surface of the fleece on the back and hindquarters of the sheep using the Pour-On Gun fitted with the fan-spray nozzle. Half the dose should be applied to the shoulders, back and flanks, and half to the rump. The distance between the nozzle and the fleece should be approximately 20 cm. Each dose will require 2 or 3 sweeps to apply.

THE PRODUCT WILL PREVENT BLOWFLY STRIKE ONLY ON AREAS COVERED BY SPRAY. One application will give 6-8 weeks protection.



Treatment of blowfly strike

Apply directly to all the affected parts at the rate of 2.5 ml per 100 –150 cm² (roughly the size of a hand). The T-bar nozzle should be used. Most strikes will require 5-10 ml. Ensure that all affected parts are treated. A single application is sufficient to ensure that larvae are expelled and killed within a few hours.

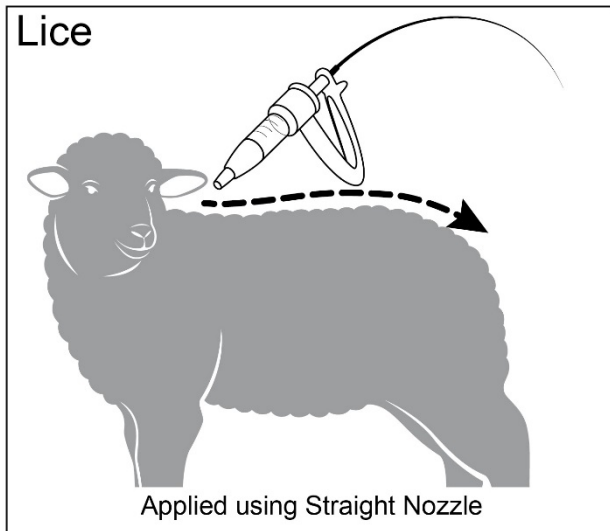
The dose should be limited to a maximum dose of 40 ml per animal.

Lice: 5 ml per 20 kg bodyweight up to a maximum of 20 ml.

Bodyweight Dose Doses per litre

Up to 20 kg	5 ml	200
21 to 40 kg	10 ml	100
41 to 60 kg	15 ml	66
Over 60 kg	20 ml	50

Using the straight nozzle on the Pour-On Gun, apply as a pin-stream from the shoulders to the rump along the middle of the backline. Sheep may be treated off-shears or at any time during the year.

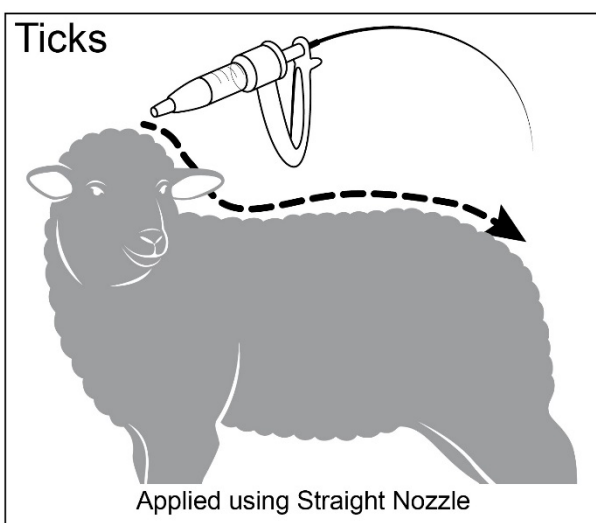


Ticks: Adult sheep and lambs greater than 10 kg: 10 ml per 20 kg bodyweight, up to a maximum of 40 ml. One treatment will give 10 weeks cover.

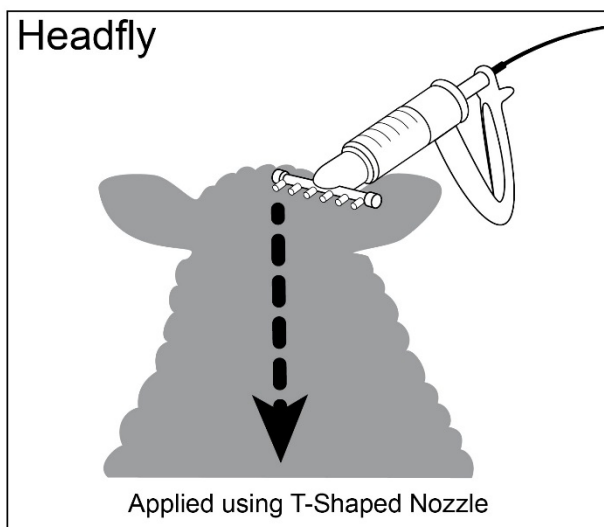
Lambs under 10 kg: 5 ml followed 3 weeks later by a 10 ml application.

<u>Bodyweight</u>	<u>Dose</u>	<u>Doses per litre</u>
Up to 10 kg	5 ml	200
11 to 20 kg	10 ml	100
21 to 40 kg	20 ml	50
41 to 60 kg	30 ml	33
Over 60 kg	40 ml	25

Using the straight nozzle on the Pour-On Gun, apply as a pin-stream from the crown of the head (see section 4.5 (i) regarding avoidance of the eyes) to the top of the rump.



Headflies: 5 ml per animal irrespective of size.
Apply to the top of the head between the ears using the T-bar nozzle.
Take care not to apply product in the sheep's eyes.



One application before the start of the headfly season will give up to 4 weeks protection

11. ADVICE ON CORRECT ADMINISTRATION

This product contains a blue dye to aid in the identification of treated animals. The colour is temporary and will fade from the fleece within 48 hours of application.

12. WITHDRAWAL PERIOD(S)

Withdrawal period(s):

Meat and offal: 8 days.

Milk: Not to be administered to animals producing milk for human consumption including non-lactating ewes in the dry period.

13. SPECIAL STORAGE PRECAUTIONS

Store in tightly closed original container, in a safe place.
Do not store above 25°C.
Do not store container in direct sunlight.
Store away from food, drink and animal feedstuffs.

14. SPECIAL WARNING(S)

Special precautions for use in animals:

Care must be taken not to apply the product right to the lamb's tail, as a ewe recognises a young lamb partly by the smell of the tail area.

Blowflies are attracted by dirty, damp wool or open wounds. The most common site for fly strike is the rump due to soiling caused by diarrhoea and urine staining. The efficacy of the product is reduced in the presence of soiled or dirty wool. Therefore, sheep must be crutched (dagged) regularly and appropriate worm control measures employed.

Take care not to apply product in the sheep's eyes. This precaution should be observed particularly when treating breeds with little wool on their heads.

Full operating and maintenance instructions, including details on the use of nozzles are supplied with each Pour-On Gun. Please read carefully before use. Maintain gun carefully to ensure accurate dosage.

For external use only

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

The veterinary medicinal product is harmful if swallowed.

Do not eat, drink or smoke whilst using the product. Wash hands immediately after use.

In case of accidental ingestion or mouth contact, immediately rinse the mouth with plenty of water and seek medical advice.

The veterinary medicinal product may cause skin, eye or respiratory irritation, and may cause hypersensitivity reactions.

Avoid skin and/or eye contact.

Use in a well-ventilated area and avoid inhaling the vapour.

Wear a disposable face-mask when applying as a fan-spray for the prevention of blowfly-strike.

Wear eye protection, protective clothing, rubber gloves and boots when applying the product and handling the animal until the product has dried.

Make sure when attaching the recommended applicator gun onto the container that the coiled retainer is secured onto the cap and the applicator.

Remove contaminated clothing immediately and wash exposed skin with plenty of clean water.

Wash splashes from skin and eyes immediately with plenty of clean water. If irritation persists seek medical advice immediately and show the package leaflet to the physician.

Avoid children from getting access to the product or treated animals.

Other precautions

Frequent and repeated use of antiparasiticides from the same class may increase risk of development of resistance.

Cypermethrin is persistent, toxic and may have the potential to bioaccumulate, Cypermethrin is thus possibly a PBT compound. Cypermethrin has been taken up on the list of 'priority substances' (Directive 2013/39/EU), which means that its presence in water bodies is monitored regularly.

Cypermethrin is extremely toxic to aquatic and dung organisms.

As a precautionary measure sheep must be kept away from watercourses for at least 12 hours following treatment.

Long term effects on dung insects caused by continuous or repeated use of pyrethroid ectoparasiticides cannot be excluded.

Given the risks to the environment the use of the product should be limited to one treatment per year per pasture.

Pregnancy and lactation:

May be used during pregnancy. Pregnant ewes must be handled with care. See section 12.

Interaction with other medicinal products and other forms of interaction:

The product must be applied only with the recommended applicator gun, as the product may have a detrimental effect on certain components of conventional dosing guns.

Overdose (symptoms, emergency procedures, antidotes):

Toxic signs in mammals are tremors, hyperexcitability, salivation, chorea, athetosis and paralysis rarely leading to death. Usually, the signs disappear rapidly and the animals recover, generally within a week.

There is no specific antidote but symptomatic therapy can be given if considered necessary.

Incompatibilities:

None known

15. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

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

Extremely dangerous to fish and other aquatic life. Do not contaminate ponds, waterways or ditches with the product or empty container.

16. DATE ON WHICH THE LABEL WAS LAST APPROVED

November 2019

17. OTHER INFORMATION

Pack sizes 1 litre, 2.5 litres or 5 litres

Not all pack sizes may be marketed.

18. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only.

POM-VPS (UK) : Prescription Only Medicines – Veterinarian, Pharmacist and SQP.

19. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

20. EXPIRY DATE

Expiry Date: EXP

The product must be used within 3 months of opening the container.

Once opened use by

21. MARKETING AUTHORISATION NUMBER(S)

Vm 50146/4019

22. MANUFACTURER’S BATCH NUMBER

BN:

Approved 19 November 2019

