LABELLING AND PACKAGE LEAFLET

<PARTICULARS TO APPEAR ON THE OUTER PACKAGE> <PARTICULARS TOAPPEAR ON THE IMMEDIATE PACKAGE>

{All labelling particulars will appear on a front and back label on the immediatepackaging (Kiwi bottle). No outer packaging will be used.}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

MoleEcto 12.5 mg/ml Pour-on for Sheep

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Cypermethrin 12.5 mg/ml (tech.) (cis:trans/80:20)

3. PHARMACEUTICAL FORM

Pour-on

4. PACKAGE SIZE

2.5L
5L

5. TARGET SPECIES

Sheep

6. INDICATION(S)

For treatment and prevention of blowfly strike, treatment of ticks and bitinglice, and treatment and control of headflies.

PREVENTION OF BLOWFLY STRIKE FOR 6-8 WEEKS
TREATMENT OF TICKS FOR 10 WEEKS

For treatment and prevention of blowfly strike, treatment of ticks with a persistent efficacy of 10 weeks (the majority of ticks killed within 3 hours), treatment of bitinglice, and treatment and control of headflies.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

FOR EXTERNAL USE ONLY.

The product must only be applied with a suitable multi-nozzle Sheep Pour-on gun (e.g. Simcro 20ml Sheep Pour-on gun) as the product may have a detrimental effecton certain components of conventional dosing guns. Full operating and maintenanceinstructions, including details on the use of nozzles, are supplied with each Pour-on Gun. Please read package leaflet carefully before use. Maintain gun carefully to ensure accurate dosage.

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.

Failure to use the product as directed may result in suboptimal parasite control.

Mothering up
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.

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.
Dosage:
BLOWFLIES
Prevention of blowfly strike

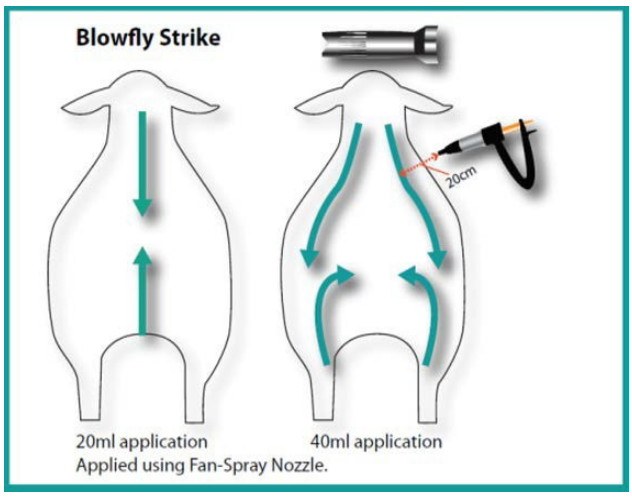
Bodyweight	Doses	Doses per 5 L pack
Up to 25 kg*	20 ml	250
25-40 kg	30 ml	166
Over 40 kg	40 ml	125

*Do not administer to animals of less than 12.5 kg bodyweight.

Apply as a fan-spray to the surface of the fleece on the back and hindquarters of the sheep using a suitable 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. Re-treat as required.



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). Use a suitable Pour-on Gun with the T-BAR NOZZLE. 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.

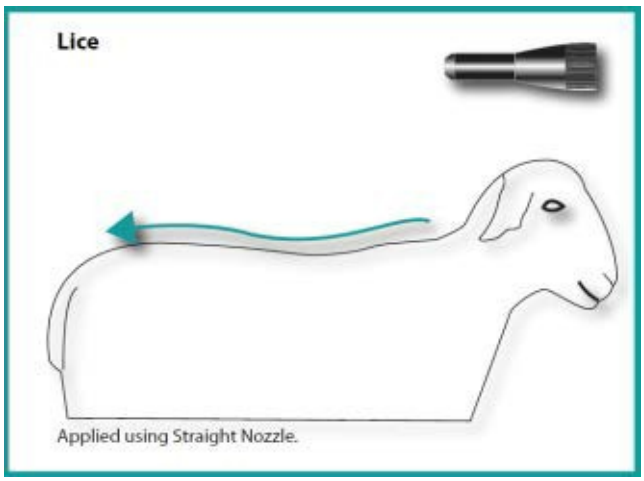
Further Information:

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.

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

Bodyweight	Doses	Doses per 5 L pack
Up to 20 kg	5 ml	1000
21-40 kg	10 ml	500
41-60 kg	15 ml	333
Over 60 kg	20 ml	250

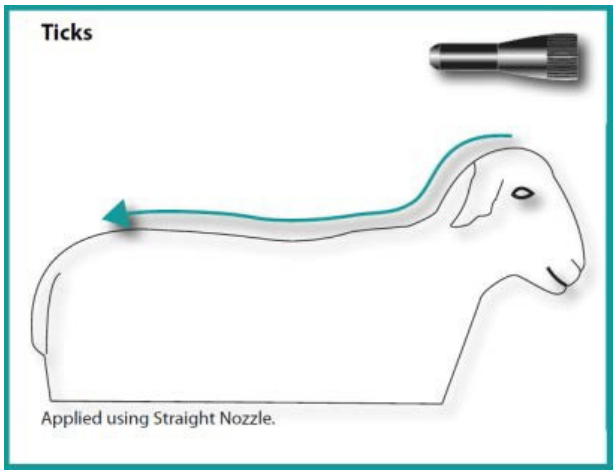
Using the STRAIGHT NOZZLE on a suitable Pour-on Gun, apply as a pin stream from the shoulders to the rump along the middle of the backline.
Sheep may be treated off-shears or at any time during the year.



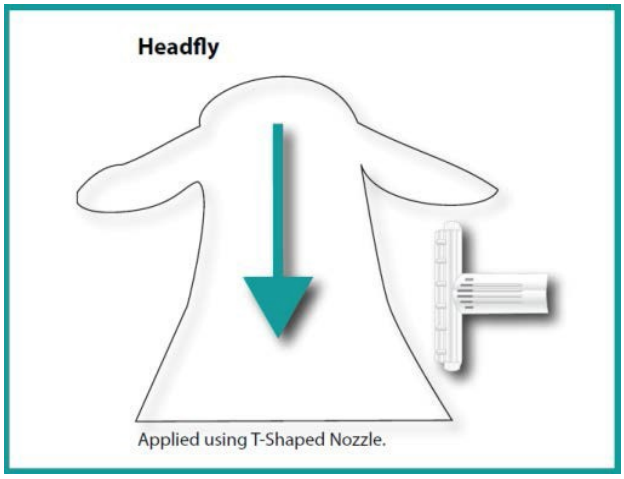
TICKS
Adult sheep and lambs over 10 kg: 10 ml per 20 kg bodyweight up to a maximum of 40 ml. One treatment will give 10 weeks cover.

Bodyweight	Doses	Doses per 5 L pack
Up to 10 kg	5 ml	1000
11-20 kg	10 ml	500
21-40 kg	20 ml	250
41-60 kg	30 ml	166
Over 60 kg	40 ml	125

Lambs under 10 kg: 5 ml followed 3 weeks later by a 10 ml application.
Using the STRAIGHT NOZZLE on a suitable Pour-on Gun, apply as a pin streamfrom the crown of the head 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 a suitable Pour-on Gun with theT-BAR NOZZLE.
Take care not to apply product in the sheep's eyes.



One application of the product before the start of the headfly season will give up to 4weeks protection. Re-treat as required.

8. WITHDRAWAL PERIOD(S)

Meat and offal: 8 days

Milk: 5 days

9. SPECIAL WARNING(S), IF NECESSARY

Contraindications
Do not use on lambs less than one week old.
Do not treat very young lambs if the weather is unseasonably hot.
Do not use for the prevention of blowfly strike in animals of less than 12.5 kg bodyweight.
Do not use in known cases of hypersensitivity to the active substance or to any of the excipients.

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

Special precautions for use
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.
To ensure administration of a correct dose, body weight should be determined as accurately as possible; accuracy of the dosing device should be checked.
Prior to application, check the Pour-On gun for correct operation and calibration.

Adverse reactions
None known.
If you notice any side effects or you think that the medicine has not worked, please inform your veterinary surgeon.

Use during pregnancy and lactation
No restrictions. Pregnant ewes must be handled with care.

Overdose
Toxic signs in mammals are tremors, hyperexcitability, salivation, abnormal involuntary movements and paralysis. Usually, the signs disappear rapidly and the animals recover, generally within 1 week.
There is no specific antidote but symptomatic therapy can be given if considered necessary

User Warnings

This product is harmful if swallowed and may cause skin, eye or respiratory irritation. This product may also cause hypersensitivity reactions.
Make sure when attaching a suitable Pour-on Gun onto the container that the coiled retainer is secured onto the cap and the applicator. Wear eye protection,

protective clothing, rubber gloves and boots when applying the product. Wear a disposable face-mask when applying as a fan-spray for the prevention of blowfly-strike.

Remove contaminated clothing immediately and wash exposed skin with plenty of clean water. Cypermethrin can be skin sensitizing and eye irritating. In a few instances operators may experience a mild tingling sensation of the skin when using the product. Wash splashes from skin immediately and thoroughly with plenty of clean water. If irritation persists seek medical advice immediately. If product splashes in eyes, flush thoroughly with water for 10 to 15 minutes and seek medical advice immediately.
Do not eat, drink or smoke whilst using the product.
Wash hands and exposed skin before eating, drinking or smoking and after work. Use in a well-ventilated area and avoid inhaling the vapour.

Environmental Warnings

Cypermethrin is toxic to dung insects. Long term effects on dung insects caused by continuous or repeated use of the product cannot be excluded.

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

10. EXPIRY DATE

Use by end { month/year}

Once opened use by:

11. SPECIAL STORAGE CONDITIONS

Store in tightly closed original container. The product must be used within 3 months of opening the container. Discard unused material. Do not store above 25˚C. Protect from direct sunlight. Store away from food, drink and animal feedstuffs.

12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTSOR WASTE MATERIALS, IF ANY

Dispose of any unused product or empty containers in accordance with guidance from your local waste regulation authority.

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

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS ORRESTRICTIONS REGARDING SUPPLY AND USE, if applicable

FOR ANIMAL TREATMENT ONLY.

POM-VPS

TO BE SUPPLIED ONLY ON VETERINARY PRESCRIPTION

POM-VPS products may only be supplied in accordance with a prescription from a Registered Qualified Person (RQP) as follows: (i) a registered veterinary surgeon; (ii)a registered pharmacist, or (iii) a registered suitably qualified person (SQP).

14. THE WORDS "KEEP OUT OF THE REACH AND SIGHT OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Elanco Europe Ltd
Form 2, Bartley Way
Bartley Wood Business
Park
Hook
RG27 9XA

16. MARKETING AUTHORISATION NUMBER

Vm 00879/4085

17. MANUFACTURER'S BATCH NUMBER

BN {number}

Site of Batch Release
Argenta Dundee Limited
Kinnoull Road
Dunsinane Industrial Estate
Dundee
DD2 3XR
United Kingdom

Available in 2.5 litre and 5 litre bottles
Not all pack sizes may be marketed

Approved: 11 March 2022