

## **SUMMARY OF PRODUCT CHARACTERISTICS**

### **1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

MoleEcto 12.5 mg/ml Pour-On for Sheep

### **2. QUALITATIVE AND QUANTITATIVE COMPOSITION**

#### Qualitative composition

#### Quantitative composition

Active substance(s):

Cypermethrin tech. (cist :trans / 80 :20)

12.5 mg/ml

Excipient(s):

Lissamine Green B (E142)

0.2 mg/ml

For a full list of excipients, see section 6.1.

### **3. PHARMACEUTICAL FORM**

Pour-on solution.

Clear blue non-aqueous solution.

### **4. CLINICAL PARTICULARS**

#### **4.1 *Target species***

Sheep.

#### **4.2 *Indications for use, specifying the target species***

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.

#### **4.3 *Contraindications***

Do not use in 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.

#### **4.4 *Special warnings for each target species***

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

#### **4.5 Special precautions for use**

i) 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.

Prior to application, check the Pour-On gun for correct operation and calibration.

For external use only.

ii) Special precautions for the person administering the veterinary medicinal product to animals

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.

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.

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

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.

iii) Other precautions

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

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

#### **4.6 Adverse reactions (frequency and seriousness)**

None known.

#### **4.7 Use during pregnancy, lactation or lay**

No restrictions, but handle pregnant sheep with care.

#### **4.8 Interaction with other medicinal products and other forms of interaction**

The product must be applied only with a suitable multi-nozzle Sheep Pour-on Gun, as the product may have a detrimental effect on certain components of conventional dosing guns.

#### **4.9 Amount(s) to be administered and administration route**

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.

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

Administer by means of a suitable Pour-on Gun as follows:

##### ***Blowflies:***

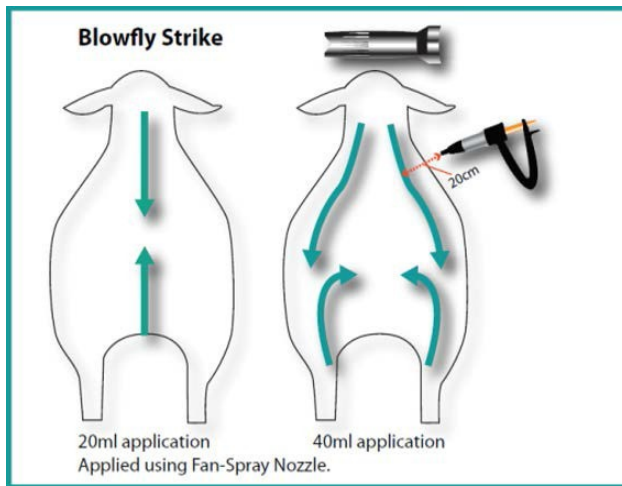
##### Prevention of blowfly strike

<u>Bodyweight</u>	<u>Dose</u>	<u>Doses per litre</u>
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.

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. Re-treat as required.



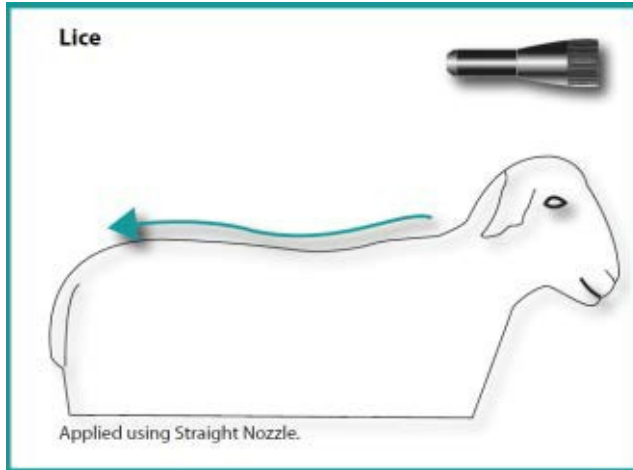
### Treatment of blowfly strike

Apply directly to all the affected parts at the rate of 2.5 ml per 100 –150 cm<sup>2</sup> (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.

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

<u>Bodyweight</u>	<u>Dose</u>	<u>Doses per litre</u>
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.

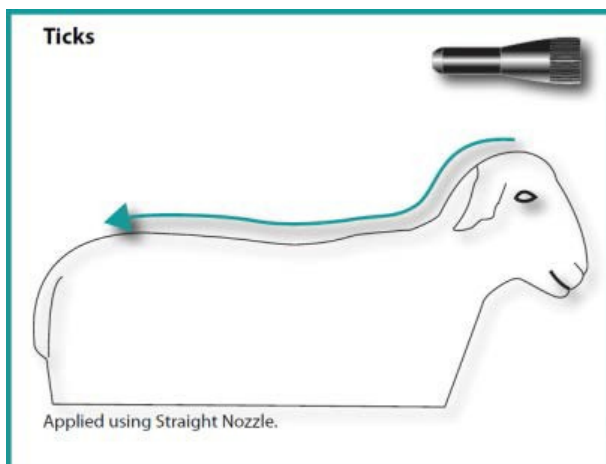


**Ticks:** Adult sheep and lambs greater than 10 kg: 10 ml per 20 kg bodyweight, up to a maximum of 40 ml. One treatment will give 10 weeks cover.

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

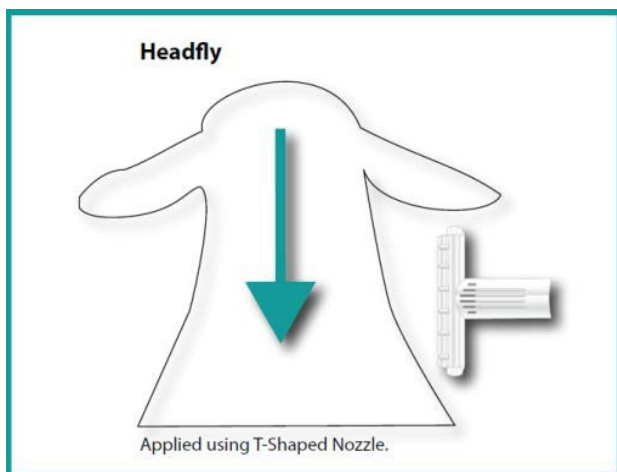
<u>Bodyweight</u>	<u>Dose</u>	<u>Doses per litre</u>
Up to 10 kg	5 ml	200
11 to 20 kg	10 ml	100
21 to 40 kg	20 ml	50
41 to 60 kg	30 ml	33
Over 60 kg	40 ml	25

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. Re-treat as required.

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.

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

Toxic signs in mammals are tremors, hyperexcitability, salivation, chorea, athetosis and paralysis. 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.

#### **4.11 Withdrawal period(s)**

Sheep (meat & offal): 8 days.

Milk: 5 days

### **5. PHARMACOLOGICAL PROPERTIES**

**Pharmacotherapeutic group:** ectoparasiticides for topical use, incl. insecticides

**ATC Vet Code:** QP53AC08

### **5.1 *Pharmacodynamic properties***

Cypermethrin is a neuropoison acting on the axons in the peripheral and centralnervous system of insects by interacting with sodium channels.

### **5.2 *Pharmacokinetic properties***

Synthetic pyrethroids are generally metabolised in mammals through ester hydrolysis, oxidation and conjugation and there is no tendency to accumulate intissues.

### **5.3 *Environment properties***

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

## **6. PHARMACEUTICAL PARTICULARS**

### **6.1 *List of excipients***

Lissamine Green B (E142)  
2-(2-Butoxyethoxy) ethanol

### **6.2 *Major incompatibilities***

None known.

### **6.3 *Shelf life***

Shelf life of the veterinary medicinal product as packaged for sale: 2 Years.  
Shelf life after first opening of the immediate packaging: 3 months.

### **6.4 *Special precautions for storage***

Do not store above 25°C.  
Protect from direct sunlight.  
Store in tightly closed original container.  
Store away from food, drink and animal feeding stuffs.

### **6.5 *Nature and composition of immediate packaging***

The product will be supplied in white, opaque, high density polyethylene 'Kiwi' bottles containing either 2.5 or 5 litres of product. They will be sealed with a 38mm polypropylene cap (screw-fit) and an integral heat induction liner. The product also contains a polypropylene spouted cap (screw-fit) with an expanded steran sealing wad.

Not all pack sizes may be marketed

**6.6 *Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products, if appropriate***

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.

**7. MARKETING AUTHORISATION HOLDER**

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

**8. MARKETING AUTHORISATION NUMBER**

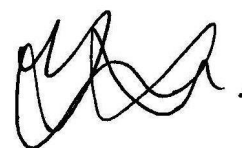
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**9. DATE OF FIRST AUTHORISATION**

13 May 2013

**10. DATE OF REVISION OF THE TEXT**

March 2022

A handwritten signature in black ink, consisting of several loops and a final horizontal stroke.

Approved: 11 March 2022