### 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Young's Vector 12.5 mg/ml Pour-on Solution

# 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains: **Active substance:** 

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

## **Excipients:**

Qualitative composition of excipients and other constituents	Quantitative composition if that information is essential for proper administration of the veterinary medicinal product
Green S Dye (E142)	0.2 mg
Butyl dioxitol	

A clear, blue solution.

## 3. CLINICAL INFORMATION

## 3.1 Target species

Sheep.

# 3.2 Indications for use for each target species

For the treatment and control of headflies. For the treatment and prevention of *Ixodes ricinus* tick infestation (one treatment will give 10 weeks cover) and treatment of biting lice in sheep. For the prevention and treatment of blowfly strike in sheep.

# 3.3 Contraindications

Do not use in lambs less than one week old.

For the prevention of blowfly strike; do not administer to animals of less than 12.5 kg bodyweight. Do not use in cases of hypersensitivity to the active substance or to any of the excipients.

# 3.4 Special warnings

None.

# 3.5 Special precautions for use

Special precautions for safe use in the target species:

Avoid treating very young lambs if the weather is unseasonably hot.

The veterinary medicinal product minimises mothering-up problems after treatment. However, care must be taken not to apply the veterinary medicinal 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 veterinary medicinal 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 the veterinary medicinal 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 applicator gun. Please read carefully before use. Maintain applicator 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:

Butyl dioxitol is slightly irritating to skin and moderately irritating to eyes.

Wear protective clothing, rubber gloves and boots when applying the veterinary medicinal product.

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

Wash splashes from skin and eyes immediately.

Do not eat, drink or smoke whilst using the veterinary medicinal product.

Wash hands and exposed skin before eating, drinking or smoking and after work.

Use in a well-ventilated area.

In a few instances operators may experience a mild tingling sensation of the face when using the veterinary medicinal product.

Avoid handling sheep immediately after treatment.

Special precautions for the protection of the environment:

Not applicable.

### 3.6 Adverse events

## Sheep:

Very rare	Application site irritation <sup>1</sup> ;
(<1 animal / 10 000 animals treated, including isolated reports):	Ataxia <sup>1</sup> , Incoordination <sup>1</sup> , Flaccid paralysis <sup>1</sup> .

<sup>&</sup>lt;sup>1</sup> Animals generally recover within a week.

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 the immediate packaging for respective contact details.

# 3.7 Use during pregnancy, lactation or lay

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

# Pregnancy:

Laboratory studies in rats and rabbits have not produced any evidence of teratogenic or mutagenic effects.

# 3.8 Interaction with other medicinal products and other forms of interaction

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

# 3.9 Administration routes and dosage

Pour-on use.

The veterinary medicinal product is administered by means of a Youngs's Endecto applicator gun as follows:

To ensure a correct dosage, bodyweight should be determined as accurately as possible.

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

Bodyweight	Dose	Doses per litre
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 applicator gun, apply as a pin-stream from 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 the T-bar nozzle.

Take care not to apply the veterinary medicinal product in the sheep's eyes.

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

### **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

<sup>\*</sup>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 applicator 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 VETERINARY MEDICINAL 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 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 the affected parts are treated. A single application is sufficient to ensure that larvae are expelled and killed within a few hours.

This veterinary medicinal product contains a blue dye to aid in the identification of treated animals. The colour is temporary and will fade from the fleece within 7 days of application, depending upon fleece length and weather conditions.

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

Toxic signs in mammals are tremors, hyperexcitability, salivation, choreoathetosis 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.

# 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

Meat and offal: 7 days

Milk: 5 days

### 4. PHARMACOLOGICAL IMMUNOLOGICAL INFORMATION

**4.1 ATCvet code :** QP53AC08

## 4.2 Pharmacodynamics

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

# 4.3 Pharmacokinetics

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

# 5. PHARMACEUTICAL PARTICULARS

### 5.1 Major incompatibilities

None known.

## 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. Store in the original container. Keep the container tightly closed. Protect from light.

Store away from food, drink and animal feeding stuffs.

# 5.4 Nature and composition of immediate packaging

2.5 litre or 5 litre white, opaque, high density polyethylene flexi-pack, closed with a white, polypropylene screw cap and surlyn coated foil induction seal.

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

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

The veterinary medicinal product should not enter water courses as cypermethrin may be dangerous for fish and other aquatic organisms.

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

Elanco GmbH.

## 7. MARKETING AUTHORISATION NUMBER(S)

VPA22020/027/001

## 8. DATE OF FIRST AUTHORISATION

21/10/2016

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

19/05/2025

# 10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the <u>Union Product Database</u> (<a href="https://medicines.health.europa.eu/veterinary">https://medicines.health.europa.eu/veterinary</a>).