

Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Young’s Vector 1.25% Pour-on solution.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Ingredient	% w/v
Cypermethrin tech. (cis:trans / 80:20)	1.25
Excipients	
Butyl Dioxitol	
Green S (E142)	0.02

3 PHARMACEUTICAL FORM

Product imported from UK: Blue Pour-on 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, and treatment of ticks and biting lice in sheep. For the prevention and treatment of blowfly strike in sheep.

4.3 Contraindications

Not to be used in lambs less than one week old.
For the prevention of blowfly strike; do not administer to animals of less than 12.5kg bodyweight.
Do not use in cases of known hypersensitivity to the active ingredient.

4.4 Special warnings for each target species

See point 4.6

4.5 Special precautions for use

Special precaution(s) for use:

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

The product minimises mothering-up problems after treatment. However, 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.

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

For external use only.

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

Operator warnings:

Butyl dioxitol is slightly irritating to skin and moderately irritating to eyes. Wear protective clothing, rubber gloves and boots when applying the 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 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 product.

Avoid handling sheep immediately after treatment.

4.6 Adverse reactions (frequency and seriousness)

Transient adverse effects may occur. These include irritation, ataxia, inco-ordination and flaccid semi-paralysis. In most of the reported literature studies and toxicity trials these signs disappeared fairly rapidly and the animals generally recovered within a week. The most severe side effects were observed in very young lambs (1-2 days old) and the product is therefore contra-indicated in lambs less than one week old.

4.7 Use during pregnancy, lactation or lay

Whilst there is no specific data available on the use of the product in pregnant ewes, laboratory studies (in rats and rabbits) have shown that cypermethrin has no teratogenic or mutagenic effect.

The product must not be used in sheep producing milk for human consumption.

4.8 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.

4.9 Amounts to be administered and administration route

The product is administered by means of a pour-on gun as follows:

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

Bodyweight	Dose	Doses per litre
Up to 20 kg	5ml	200
21 to 40kg	10ml	100
41 to 60kg	15ml	66
Over 60kg	20ml	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 over 10kg: 10ml per 20kg bodyweight, up to a maximum of 40ml. Lambs under 10kg: 5ml followed 3 weeks later by a 10ml application.

Bodyweight	Dose	Doses per litre
Up to 10kg	5ml	200
11 to 20kg	10ml	100
21 to 40kg	20ml	50
41 to 60kg	30ml	33
Over 60kg	40ml	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: 5ml 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 of the 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 25kg*	20ml	50
25 to 40kg	30ml	33
Over 40kg	40ml	25

*Do not administer to animals of less than 12.5kg 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 20cm. 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 2.5ml per 100 –150cm² (roughly the size of a hand). The T-bar nozzle should be used. Most strikes will require 5-10ml. Ensure that all affected parts are treated. A single application is sufficient to ensure that larvae are expelled and killed within a few hours.

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 7 days of application, depending upon fleece length and weather conditions.

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

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.

4.11 Withdrawal Period(s)

Meat: Animals must not be slaughtered for human consumption during treatment. Sheep may be slaughtered for human consumption only after 8 days from the last treatment.

Milk: Not to be administered to animals producing milk for human consumption.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

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

5.2 Pharmacokinetic properties

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

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Green S dye (E142)

Butyl dioxitol

6.2 Incompatibilities

None.

6.3 Shelf-life

18 months.

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

The shelf life expiry date of this product is the date shown on the container and outer carton of the product as marketed in the country of origin.

6.4 Special precautions for storage

Store in original container, tightly closed in a safe place.

Do not store above 25°C. Protect from light.

Store away from food, drink and animal feedingstuffs.

6.5 Nature and composition of immediate packaging

A blue-coloured non-aqueous solution contained within either a 2.2 or 5 litre white, opaque, polyethylene container, closed with a blue, polyethylene screw cap, with an integral induction seal,

OR

A blue-coloured non-aqueous solution contained within either a 2.2 or 5 litre white, opaque, polyethylene container, closed with a blue, polypropylene hinged tamper evident lid.

6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials

Harmful to fish.

Harmful to aquatic invertebrates and may have harmful effects to dung fauna and insects. Do not contaminate ponds, waterways or ditches with the product or used container.

Wash out container thoroughly. Unused product or waste material should be disposed of in accordance with current practice for pharmaceutical waste under national waste disposal regulations.

7 MARKETING AUTHORISATION HOLDER

Cross Vetpharm Group Ltd.,
Broomhill Road,
Tallaght,
Dublin 24.

8 MARKETING AUTHORISATION NUMBER(S)

PVPA 10960/002/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

17th October 2008

10 DATE OF REVISION OF THE TEXT