

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

DYSECT Sheep Pour-On
alphacypermethrin 12.5 g/l pour-on solution,

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance

Alphacypermethrin 12.5 g/l

Excipients

Copper Chlorophyll Complex (E141) 0.06 %w/v

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Pour-on solution.
Clear dark green liquid free from solids.

4. CLINICAL PARTICULARS

4.1 Target species

Sheep and Lambs

4.2 Indications for use, specifying the target species

For the control and treatment of blow fly strike, on sheep and lambs and for the treatment of lice and ticks on sheep. Reduces the incidence of headfly strike in sheep and lambs for up to 6 weeks.

4.3 Contraindications

Do not treat lambs under one week old and avoid treating animals in very hot weather.

4.4 Special warnings

None.

4.5 Special precautions for use

- i. Special precautions for use in animals

For external use only.

Because alphacypermethrin is retained in the wool grease of the fleece, it is recommended that the product be applied to sheep with a minimum wool length of 1.0cm.

- ii. Special precautions to be taken by the person administering the veterinary medicinal product to animals

Wear waterproof apron and boots and impervious gloves when applying the product and when handling recently treated animals

Use the product in a well-ventilated area

Wash any splashes from the skin and eyes immediately, using plenty of water.

Remove heavily contaminated clothing immediately and wash before re-use.

Wash hands and exposed skin with soap and water after treatment and before eating drinking and smoking.

4.6 Adverse reactions (frequency and seriousness)

Alphacypermethrin pour-on occasionally causes temporary irritation, lasting between 24 and 72 hours, in cattle. However no significant adverse reactions were recorded with sheep during the field trials for this product.

Discolouration of the fleece may be observed in some sheep from approximately 6 to 8 weeks after treatment.

4.7 Use during pregnancy, lactation or lay

Alphacypermethrin has low toxicity to mammals. There have been no tests of the effects of alphacypermethrin on foetal or lamb development.

4.8 Interaction with other medicinal products and other forms of interaction

None known.

4.9 Amounts to be administered and administration route

The product is applied at a rate of 40 mls for animals weighing 25 kg or more, and 25 mls for animals weighing less than 25 kg. The dose is applied using an adjustable dosing gun fitted with a T-bar with 3 or 4 outlets and is applied directly onto the wool in a band from the back of the head to the base of the tail. For the reduction of headfly strike 5mls per animal is applied between the horns, irrespective of size of the animal.

Blowfly - For the control of blowfly a single application will normally provide 8 to 10 weeks protection. Re-treatment may be necessary after this period. For the treatment of blowfly strike, a single treatment applied to the infected area will ensure blowfly larvae are killed.

Ticks - A single treatment will normally provide control of ticks for 8 to 12 weeks.

Headfly - A single treatment will reduce the incidence for up to 6 weeks.

Lice - A single treatment will normally kill all lice.

PEST	DOSAGE (ml)	
	SHEEP (>25KG)	LAMBS (<25KG)
Blowfly	40	25
Lice	40	
Ticks	40	
Headfly	5	5

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

No adverse reactions were recorded in double dose exposure trials.

4.11 Withdrawal period(s)

Meat: 49 days

Milk: not for use in sheep producing milk for human consumption.

5. PHARMACOLOGICAL PROPERTIES

Active ingredient: alphacypermethrin

Therapeutic Group: ectoparasiticides; insecticides and repellents; pyrethrins; cypermethrin (ATC classification index: QP53AC08)

Pharmacological action: insecticide

Substance group: alpha-cyanopyrethroids

Mechanism of action: inhibits neural transmission in insects

5.1 Pharmacodynamic properties

Alphacypermethrin is a synthetic pyrethroid, which works as an insecticide and repellent by inhibiting neural transmission in insects.

5.2 Pharmacokinetic particulars

Alphacypermethrin is lipophilic and is retained in the wool grease of the sheep fleece to provide protection from blowflies for up to 8 to 10 weeks.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Copper Chlorophyll Complex (E141)
Phytorob 926/67
Benzoic acid

6.2 Incompatibilities

None known.

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 18 months.

6.4. Special precautions for storage

Do not store above 25°C.
Store in a dry place.
Store upright in the tightly closed original container.
Protect from direct sunlight.
Do not freeze.
If contents freeze they must be thawed and thoroughly mixed before use.
Store away from food, drink and animal feeding stuffs.

6.5 Nature and composition of immediate packaging

The container is a fluorinated HDPE backpack dispenser of 2.5 litre and 5 litre content.

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

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

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

7. MARKETING AUTHORISATION HOLDER

Pfizer Limited
Ramsgate Road
Sandwich
Kent
CT13 9NJ

8. MARKETING AUTHORISATION NUMBER

Vm 00057/4414

9. DATE OF FIRST AUTHORISATION

Date: 10-Dec-1999

10. DATE OF REVISION OF THE TEXT

Date: September 2011