

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Vetrazin 6% w/v Pour-On Solution

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

<u>Active ingredients</u>	<u>% w/v</u>
Cyromazine	6.000

Excipients:

Methyl parahydroxybenzoate	0.081
Ethyl parahydroxybenzoate	0.017
Propyl parahydroxybenzoate	0.016
Ponceau 4 R (E124, as colorant)	0.008

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Pour-on solution.
Clear red solution.

4. CLINICAL PARTICULARS

4.1 Target species

Sheep.

4.2 Indications for use, specifying the target species

For the prevention of blowfly strike (*Lucilia sericata*) in sheep and lambs for 10 weeks after dosing.

4.3 Contraindications

None.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

- i. Special precautions for use in animals

For external use only.

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

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

Wear synthetic rubber gloves when transferring the product from one container to another.

Wash hands and exposed skin before meals and after work.

Wash splashes from skin and eyes immediately.

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

4.6 Adverse reactions (frequency and seriousness)

None.

4.7 Use during pregnancy, lactation or lay

Not contra-indicated.

4.8 Interaction with other medicinal products and other forms of interaction

None known.

4.9 Amounts to be administered and administration route

WHOLE BODY PROTECTION

To be applied as a "pour-on" along both side of the animal's spine from mid-shoulder to rump paying particular attention to the crutch area. The product must be applied with the ELANCO POUR-ON GUN. The applicator gun should be set to deliver half the required dose in one squirt. One squirt should then be applied along the spine from the middle of the shoulder to the rump and a second squirt around the crutch and tail area.

To be applied at the following rates:

<u>Weight of Animal</u>	<u>Dose</u>
11 – 15 kg	15 ml
16 – 20 kg	20 ml
21 – 30 kg	30 ml
31 – 40 kg	40 ml
over 41 kg	50 ml

PROTECTION AGAINST TAIL/CRUTCH STRIKES ONLY

Where experience shows that animals are susceptible to tail/crutch strikes only and body strikes are not a problem, protection against fly strike in the tail/crutch area can be achieved by applying Vetrazin Pour-on to this area alone.

To be applied at the following rates:

<u>Weight of Animal</u>	<u>Dose</u>
11 – 15 kg	7.5 ml
16 – 20 kg	10 ml
21 – 30 kg	15 ml
31 – 40 kg	20 ml
over 41 kg	25 ml

Animals may be treated every 8-10 weeks under conditions of extreme blowfly challenge.

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

Not applicable.

4.11 Withdrawal period(s)

Sheep (meat and offal): 28 days

Not to be used on animals producing milk for human consumption

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Ectoparasiticide for topical use.

ATCvet code: QP53AX

5.1 Pharmacodynamic properties

Insect growth regulator. Not pharmacologically active in mammals.

5.2 Pharmacokinetic particulars

Dermal absorption rate a maximum of 10% of dose over 8 hours. Cyromazine rapidly excreted in mammals and birds.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Methyl parahydroxybenzoate
Ethyl parahydroxybenzoate
Propyl parahydroxybenzoate
Ponceau Red (E142)
Lactic acid edible 80
Acetic acid glacial
Propylene glycol
Macrogol cetostearyl ether
Silicone emulsion
Water de-ionised

6.2 Incompatibilities

None known.

6.3 Shelf life

Shelf life of veterinary product as packaged for sale: 3 years.

6.4 Special precautions for storage

Do not store above 25°C.
Protect from frost.
Protect from light.
Shake the container before use.
Store in tightly closed original container.
Store away from food, drink and animal feedstuffs.

6.5 Nature and composition of immediate packaging

Packs of 2.5 litre, 5 litre, 10 litre and 25 litre natural HDPE bottles closed with polyethylene induction heat seals and white HDPE screw caps.

Packs of 0.8 litre, 2.2 litre and 5 litre in white HDPE bottles closed with polyethylene induction heat seals and blue HDPE screw caps

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 the use of such veterinary medicinal products should be disposed of in accordance with local requirements.

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

7. MARKETING AUTHORISATION HOLDER

Elanco Europe Ltd
Lilly House
Priestley Road
Basingstoke
Hampshire
RG24 9NL

8. MARKETING AUTHORISATION NUMBER

Vm 00879/4023

9. DATE OF RENEWAL OF THE AUTHORISATION

23 December 2003

10. DATE OF REVISION OF THE TEXT

January 2017

A handwritten signature in black ink, appearing to be 'Alan', with a horizontal line underneath.

Approved: 26 January 2017