Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Vetrazin 60 mg/ml Pour-On Solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active ingredient		
Cyromazine (Tech)	60	mg
Excipients		
Preservatives:		
Methyl parahydroxybenzoate (E218)	0.81	mg
Ethyl parahydroxybenzoate (E214)	0.174	mg
Propyl parahydroxybenzoate (E216)	0.116	mg
Ponceau 4R (E124) as colourant	0.08	mg

For a full list of excipients see section 6.1.

3 PHARMACEUTICAL FORM

Pour-On Solution.
A clear, pink solution.

4 CLINICAL PARTICULARS

4.1 Target Species

Ovine

4.2 Indications for use, specifying the target species

For the prevention of blowfly strike (*Lucilia serricata*) in ovines.

4.3 Contraindications

Do not use in case of known hypersensitivity to the active substance.Do not use in sheep producing milk for human consumption.

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.
The product should be applied before an anticipated blowfly challenge, and not on established strikes.
Established strikes should be treated with an authorised product according to label instructions.
Dirty sheep or lambs should be dagged prior to treatment. Sheep or lambs which scour after treatment should be dagged.

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.
In case of accidental splashes, wash product from skin and eyes immediately.
Do not eat, drink or smoke whilst using the product.

4.6 Adverse reactions (frequency and seriousness)

None known.

4.7 Use during pregnancy, lactation or lay

Not contraindicated.

4.8 Interaction with other medicinal products and other forms of interactions

None known.

4.9 Amounts to be administered and administration route

Whole body protection, for up to 12 weeks.
To be applied as a pour on along both sides of the animals spine from mid shoulder to rump and to the crutch area. The product must be applied with an Elanco Pour On Gun.

To be applied at the following rates:

Weight of AnimalDose
11 - 15 kg 15 ml
16 - 20 kg 20 ml

21 - 30 kg 30 ml
31 - 40 kg 40 ml
41 kg+ 50 ml

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

Not applicable

4.11 Withdrawal period(s)

Meat and offal: 28 days.
Milk: Not to be used on sheep producing milk for human consumption.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Ectoparasiticides for topical use
ATCvet code: QP53A

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

Macrogol cetostearyl ether
Lactic acid
Glacial acetic acid
Propylene glycol
Methylparaben (E218)
Ethylparaben (E214)
Propylparaben (E216)
Silicone emulsion
Ponceau 4R (E124)
Water

6.2 Major incompatibilities

None known.

6.3 Shelf-life

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

6.4 Special precautions for storage

Protect from direct sunlight.
Protect from frost.

6.5 Nature and composition of immediate packaging

2.2 and 5 litre HDPE polyethylene flexipacks with polyethylene screw on caps.
Not all pack sizes may be marketed.

6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products

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

7 MARKETING AUTHORISATION HOLDER

Elanco GmbH
Heinz-Lohmann-Strasse 4
27472 Cuxhaven
Germany

8 MARKETING AUTHORISATION NUMBER(S)

VPA22020/026/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 1st October 1999
Date of last renewal: 30th September 2009

10 DATE OF REVISION OF THE TEXT

July 2018