SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Dicyclanil Elanco 5% Pour-on Suspension

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

100 ml suspension contains:

Active substance:	Dicyclanil (ISO)	5.00 g
Colouring matter:	Ponceau 4R	E124
Preservatives	Methylparaben	E218
	Propylparaben	E216
	Butylated hydroxytoluene	E321

For a full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Pour-on suspension

4. CLINICAL PARTICULARS

4.1 Target species

Sheep

4.2 Indications for use, specifying the target species

Prevention of blowfly strike due to *Lucilia sericata* on sheep.
Prevention of blowfly strike due to *Wohlfahrtia magnifica* on sheep.

4.3 Contraindications

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

4.4 Special warnings for each target species

None

4.5 Special precautions for use

i) Special precautions for use in animals

The product is best applied before an anticipated blowfly challenge, or when a blowfly challenge is identified on or in the vicinity of the farm. Established strikes may require a separate treatment with a knockdown insecticide.

It is recommended that animals with dirty back-ends are dagged prior to application. If dagging or crutching is undertaken in the weeks following application, these animals should be re-treated, otherwise protection could be lost.
Do not apply during heavy rainfall, or when such conditions are expected. The resulting wash out may reduce the protection period.
The use of Dicyclanil Elanco 5% Pour-on Suspension has harmful effects on dung flies.

Treated sheep **must** be kept away from watercourses for at least one hour after treatment. There is a **serious** risk to aquatic life if this advice is not followed.

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

- Operators should wear synthetic rubber gloves, a face mask and PVC trousers when applying the product.
- In case of skin contact remove contaminated clothing and thoroughly wash the affected parts of the body with soap and water.
- In case of eye contact rinse eyes with clean water for several minutes and contact physician for advice.
- In case of ingestion call for medical advice.
- Always wash hands with soap and water after handling sheep and before eating and drinking or smoking.
- Wash hands and exposed skin after working with recently treated sheep.
- Do not eat, drink or smoke whilst using the product.

<u>Handling sheep in the weeks following treatment:</u>
- Do not shear sheep in the 3 months after treatment.
- Handle sheep as little as possible after treatment as residues remain on the fleece for some weeks.
- If you need to handle sheep after treatment, wear coveralls and Wellington boots. If sheep are wet also wear waterproof trousers and coat.

4.6 Adverse reactions (frequency and seriousness)

None known.

4.7 Use during pregnancy, lactation or lay

The safety of the veterinary medicinal product has not been established during pregnancy or lactation. Use only accordingly to the benefit/risk assessment by the responsible veterinarian. Laboratory studies in rats and rabbits have not shown any evidence of a teratogenic, foetotoxic or maternotoxic effects.

4.8 Interaction with other medicinal products and other forms of interaction

None known.

4.9 Amounts to be administered and administration route

For external use only.

Dicyclanil Elanco 5% Pour-on Suspension is applied according to the following recommendations:

Body weight (kg)	Dose Volume (ml)
10-20	**20**
21-30	**25**
31-50	**30**
>50	**35**

(Guide dose volumes correspond to 0.6 – 2 ml (30 – 100 mg dicyclanil) per kg bodyweight.)

Shake the container well before use.

Dicyclanil Elanco 5% Pour-on suspension must be applied with a manual or automatic dosing gun (e.g. Elanco Pour-on gun), with a spray nozzle, which guarantees the correct spreading of the product on the fleece. Best results will be achieved by holding the gun approximately 45 cm from the sheep during application. Apply as a fan spray along the spine of the animal in a band at least 10 cm wide from the middle of the shoulders and in an arc around the crutch and tail. Half the dose should be applied along the spine with the remainder over the tail and crutch area.

Dicyclanil Elanco 5% Pour-on suspension is administered once, before predicted Wohlfahrtia fly activity, or before or at the beginning of Lucilia fly activity. Dicyclanil Elanco 5% Pour-on suspension will protect against blowfly strike caused by Wohlfahrtia or Lucilia flies for 16 weeks. In individual cases, a strike may occur earlier; therefore, it is good practice to check animals regularly for blowfly strike.

Do not shear sheep in the 3 months after treatment.

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

An overdose of up to at least 5 times the recommended dose does not lead to any signs of local or systemic intolerance. An antidote is not known.

4.11 Withdrawal period(s)

Meat and offal: 40 days
Not permitted for use in lactating animals producing milk for human consumption.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Other ectoparasiticides for topical use.
ATC vet code: QP53AX24.

5.1 Pharmacodynamic properties

The mode of action of dicyclanil is not known but it is apparently similar to that of cyromazine, a triazine derivative. Similar to the benzoylphenylureas (BPU) it interferes with moulting and pupation but without acting directly on the chitin synthesis. Dicyclanil prevents the moult from the first to the second larval instar of Lucilia spp. and Wohlfahrtia spp.

5.2 Pharmacokinetic particulars

After 7 days post dosing, approximately 5% of the dose was absorbed and eliminated in urine and faeces. Systemic absorption varies with such factors as wool density and length, and sheep breed. Peak blood levels were observed between 12 and 48h post dose, accounting for <0.025 mg dicyclanil equivalents/kg.

In experimental residue depletion studies, absorbed radioactivity was widely distributed throughout the body. Highest half lives were found in liver and kidney being 13 and 10 days respectively.
In muscle, fat and wool, unchanged dicyclanil was found to be the major residue, whereas in liver and kidney the descyclopropyl dicyclanil was found to be the major residue together with unchanged dicyclanil.

Environmental properties

The use of Dicyclanil Elanco 5% Pour-on suspension has harmful effects on dung flies.

Treated sheep **must** be kept away from watercourses for at least one hour after treatment. There is a **serious** risk to aquatic life if this advice is not followed.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Polysorbate 20
Pemulen TR-2NF
Methyl parahydroxybenzoate (E 218)
Propyl parahydroxybenzoate (E 216)
Disodium edetate
Butylated hydroxytoluene (E 321)
Myverol 18-92
Fractionated coconut oil
Propylene glycol
Ponceau 4R (E124)
Sodium hydroxide
Purified water

6.2 Major Incompatibilities

Not applicable.

6.3 Shelf -life

Shelf life of the veterinary medicinal product as packaged for sale: 5 years.

Shelf life after first opening the immediate packaging: 1 year

6.4 Special precautions for storage

Protect from direct sunlight.
Protect from frost.
Store in the original container.
Keep the container tightly closed.

6.5 Nature and composition of immediate packaging

The pack is composed of pigmented white opaque polyethylene back pack container with blue polypropylene screw cap, containing 0.8, 2.2 or 5 litres of finished product.

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 product or waste material should be disposed of in accordance with national requirements.
Dicyclanil Elanco 5% Pour-on suspension should not enter water courses as this may be dangerous for fish and other aquatic organisms.

7. MARKETING AUTHORISATION HOLDER

Elanco Europe Ltd
Form 2, Bartley Way
Bartley Wood Business Park
Hook
RG27 9XA
United Kingdom

8. MARKETING AUTHORISATION NUMBER

Vm 00879/5001

9. DATE OF FIRST AUTHORISATION

29 October 2021

10. DATE OF REVISION OF THE TEXT

29 October 2021

Approved 29 October 2021