SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

CLIK 50 mg/ml Pour-on Suspension for Sheep

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance:

Dicyclanil	50 mg

Excipients:

Ponceau 4R (E124)	0.05 mg
Methy parahydroxybenzoate (E218)	1.50 mg
Propyl parahydroxybenzoate (E216)	3.00 mg
Butylated hydroxytoluene (E321)	0.50 mg

For a full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Pour-on Suspension
Pink-coloured 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

Unnecessary use of antiparasitics or use deviating from the instructions given in the SPC may increase the resistance selection pressure and lead to reduced efficacy. The decision to use the product should be based on confirmation of the parasitic species and burden, or of the risk of infestation based on its epidemiological features, for each flock.

4.5 Special precautions for use

i). Special precautions for use in animals

The veterinary medicinal 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.

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 veterinary medicinal 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 accidental ingestion seek medical advice immediately and show the package leaflet or the label to the physician.
- 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 veterinary medicinal 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.

<u>Special precautions for the protection of the environment</u>:
The use of the veterinary medical product has harmful effects on dung flies.
Treated sheep **must** be kept away from watercourses for at least one hour after treatment. There is **serious** risk to aquatic life if this advice is not followed.

iii). Other precautions

None.

4.6 Adverse reactions (frequency and seriousness)

Target species: Sheep.

None known.
Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either

the marketing authorisation holder or the national competent authority via the national reporting system. See also the last section of the package leaflet for contact details.

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 according to the benefit/risk assessment by the responsible veterinarian. Laboratory studies in rats and rabbits have not produced any evidence of a teratogenic, foetotoxic or maternotoxic effects.

4.8 Interaction with other medicinal products and other forms of interaction

None known.

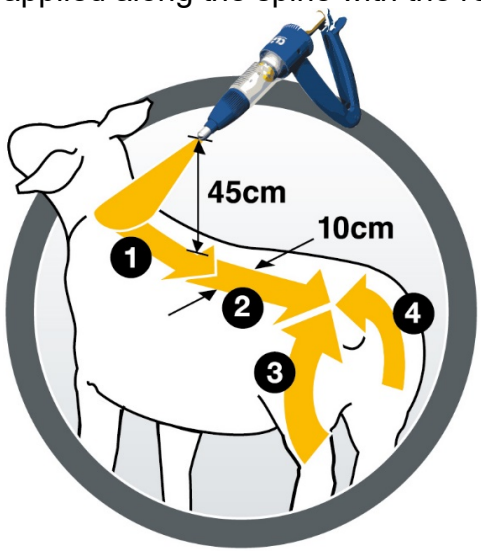
4.9 Amount(s) to be administered and administration route

For external use only.

The veterinary medicinal product 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.
The veterinary medicinal product 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 using a 4 stroke method as shown in the pictogram 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.



The veterinary medicinal product is administered once, before predicted Wohlfahrtia fly activity, or before or at the beginning of Lucilia fly activity. The veterinary medicinal product 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 authorised for use in 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.

5.3 Environmental properties

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

Medicines should not be disposed of via wastewater.
The product should not enter water causes as dicyclanil may be dangerous for fish and other aquatic organisms.
Any unused veterinary medicinal product or waste material 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
Groden
27472 Cuxhaven
Germany

8. MARKETING AUTHORISATION NUMBER

Vm 52127/5093

9. DATE OF FIRST AUTHORISATION

15 March 2001

10. DATE OF REVISION OF THE TEXT

May 2025

11. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription

POM-VPS

Gavin Hall

Approved: 22 May 2025