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:

Qualitative composition of excipients and other constituents:	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Methyl Parahydroxybenzoate (E218)	1.50 mg
Propyl Parahydroxybenzoate (E216)	3.00 mg
Butylated Hydroxytoluene (E321)	0.50 mg
Ponceau 4R (E124) Sodium	0.05 mg
Polysorbate 20	
Acylic acid copolymer (Pemulen TR-2NF)	
Disodium Edetate	
Distilled monoglyceride (Myverol 18-92)	
Medium-Chain Triglycerides (Fractionated Coconut Oil)	
Propylene Glycol	
Sodium Hydroxide	
Purified Water	

Pink-coloured pour-on suspension.

3. CLINICAL INFORMATION

3.1 Target species

Sheep.

3.2 Indications for use for each target species

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

3.3 Contraindications

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

3.4 Special warnings

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.

3.5 Special precautions for use

Special precautions for safe use in the target species:

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.

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.

Handling sheep in the weeks following treatment:

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.

Special precautions for the protection of the environment:

The use of this veterinary medicinal 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.

Other precautions:

None.

3.6 Adverse events

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 package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy and lactation:

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 teratogenic, foetotoxic, or maternotoxic effects.

3.8 Interaction with other medicinal products and other forms of interaction

None known.

3.9 Administration routes and dosage

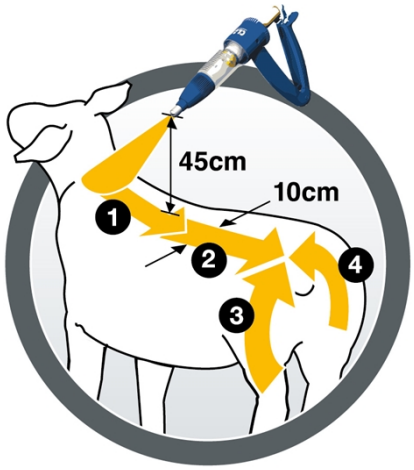
For external use only.
The veterinary medicinal product is applied according to the following recommendations:

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.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

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.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 Withdrawal periods

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

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code:

ATC vet code: QP 53AX24.

4.2 Pharmacodynamics

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.

4.3 Pharmacokinetics

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. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Not applicable.

5.2 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.

5.3 Special precautions for storage

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

5.4 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.

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

Medicines should not be disposed of via wastewater.

The veterinary medicinal product should not enter water courses as dicyclanil may be dangerous for fish and other aquatic organisms.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

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

7. MARKETING AUTHORISATION NUMBER

Vm 00879/3008

8. DATE OF FIRST AUTHORISATION

15 March 2001

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

April 2023

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

Approved: 17 April 2023