SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

CLiKZiN 12.5 mg/ml Pour-On Suspension for Sheep

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance:
Each ml contains:
Dicyclanil 12.5 mg

Excipients:

Qualitative composition of excipients and other constituents:	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Quinoline yellow (E104)	0.05 mg
Patent blue V (E131)	0.05 mg
Methyl Parahydroxbenzoate (E218)	1.50 mg
Propyl Parahydroxybenzoate	3.00 mg
Butylated Hydroxytoluene (E321)	0.50 mg
Polysorbate 20	
Acrylic acid copolymer	
Disodium edetate	
Distilled monoglycerides	
Triglycerides, medium chain	
Propylene glycol	
Sodium hydroxide	
Purified water	

Green 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 on sheep due to *Lucilia sericata.*

3.3 Contraindications

Do not use in cases of hypersensitivity to the active substance or to any of the excipients.

3.4 Special warnings

None.

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 or crutched 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:

- Redness and irritation may develop after skin or eye contact with the veterinary medicinal product.
- Contact with skin and eyes should be avoided.
- Personal protective equipment consisting of synthetic rubber gloves and PVC trousers should be worn when handling 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, wash immediately with clean water.
- Always wash hands and exposed skin with soap and water after work.
- Do not eat, drink or smoke whilst using the veterinary medicinal product.
- It is good agricultural practice to minimise handling of sheep after treatment. If you need to handle sheep within 2 months after treatment, wear synthetic rubber gloves and long trousers or coveralls. If sheep are wet wear waterproof trousers.

Special precautions for the protection of the environment:

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.

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:

Bodyweight (kg)	Dose Volume (ml)
10 - 20	20
21 – 30	24
31 - 50	30
>50	36

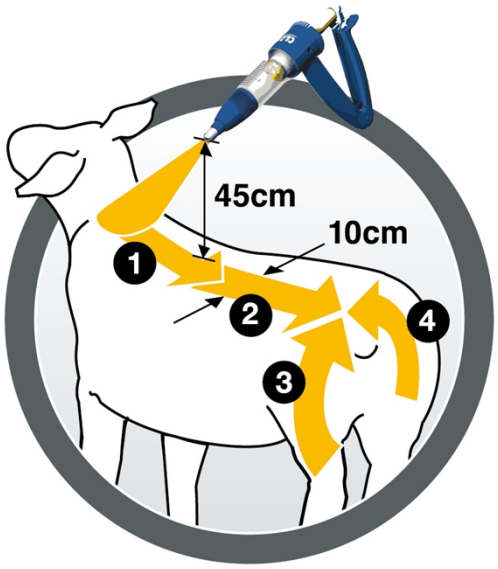
(Guide dose volumes correspond to 0.7–2 ml [7.5–25 mg dicyclanil] per kg bodyweight.)

To ensure administration of a correct dose, body weight should be determined as accurately as possible; accuracy of the dosing device should be checked.

If animals are to be treated collectively rather than individually, they should be grouped according to their bodyweight and dosed accordingly, in order to avoid under- or overdosing.

Recommended for treatment in sheep 3 weeks post shearing. Shake the container well before use.
The veterinary medicinal product must be applied with a manual or automatic dosing gun, fitted 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 theanimal in bands 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 should be administered before or at the start of predicted fly activity but is also suitable for use during the fly season.
The veterinary medicinal product will protect against fly strike for 8 weeks. It is good agricultural practice to check animals regularly for fly strike.

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

An overdose of up to at least 20 times the recommended dose does not lead to any signs of local or systemic intolerance.
No antidote is 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: 7 days.
Not authorised for use in animals producing milk for human consumption.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QP53AX24

4.2 Pharmacodynamics

Dicyclanil prevents the moult from the first to the second larval instar of *Lucilia* spp. It is less effective against later larval stages and does not have any adulticide action. The mode of action of dicyclanil is believed to be similar to that of the triazine compounds.

4.3 Pharmacokinetics

In studies with a more concentrated 5% (w/v) formulation, after 7 days post dosing, approximately 5% of the dose was absorbed and eliminated in urine and faeces. Peak blood levels were observed between 12 and 48 hours post dose, accounting for <0.025 mg dicyclanil equivalents/kg.

In experimental metabolism studies, absorbed radioactivity was widely distributed throughout the body. Longest half-lives were found in liver and kidney being 13 and10 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.

In field residue depletion studies on sheep with the veterinary medicinal product, residue levels at day 7 were very low (at maximum 31.9 and 30.7 µg/kg in liver and kidney, respectively, and no quantifiable residues found in muscle or fat), indicating minimal systemic absorption.

Environmental properties

The use of the veterinary medicinal product has harmful effects on dung flies and beetles.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 3 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, away from food, drink and animal feedstuffs.
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 is dangerous for aquatic organisms.

Do not contaminate ponds or other waterways with product of empty containers.

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 00879/3009

8. DATE OF FIRST AUTHORISATION

15 September 2010

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

May 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 16 May 2023