

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

CLiK Extra 65 mg/ml Pour-On Suspension for Sheep

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance: Dicyclanil 65 mg

Excipients:

1.50 mg

Methyl parahydroxybenzoate (E218)

Propyl parahydroxybenzoate 3.00 mg

Butylated hydroxytoluene 0.50 mg

Ponceau 4R 0.05 mg

For the full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Pink coloured suspension

4. CLINICAL PARTICULARS

4.1 Target Species

Sheep

4.2 Indications for use, specifying the target species

Prevention of blowfly strike on sheep caused by *Lucilia sericata* or *Wohlfahrtia magnifica*.

4.3 Contraindications

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

4.4 Special warnings for each target species

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 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.

4.5 Special precautions for use

Special precautions for use in animals

None

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 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 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 product.

Residues remain on the fleece for some time after treatment, therefore, it is good agricultural practice to minimise handling of sheep after treatment. If you need to handle sheep within 3 months after treatment, wear synthetic rubber gloves and long trousers or coveralls. If sheep are wet wear waterproof trousers.

Do not shear sheep in the 3 months after treatment.

Other precautions

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.

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 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.

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.

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 |

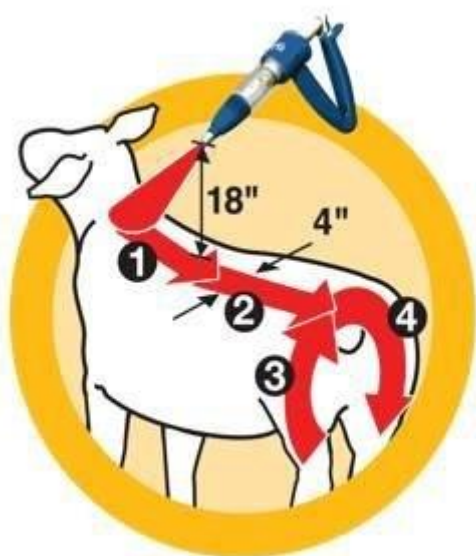
Guide dose volumes correspond to 0.6 – 2 ml [39 – 130 mg dicyclanil] per kg bodyweight.)

To ensure administration of a correct dose, bodyweight 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 with any wool length, including off-shears. Shake the container well before use.

Do not dilute with water.

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 along the spine of the animal 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 applied before, or at the start of, predicted fly activity.

The veterinary medicinal product will protect against fly strike for 19 weeks. It is good agricultural practice to check animals regularly for fly strike.

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

An overdose of up to at least 4 times the recommended dose does not lead to any signs of local or systemic intolerance.
No antidote is known.

4.11 Withdrawal Period(s)

Meat and offal: 40 days

Not authorised for use in animals producing milk for human consumption.

5. PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

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

5.1 Pharmacodynamic properties

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 adulticidal action. The mode of action of dicyclanil is believed to be similar to that of the triazine compounds.

5.2 Pharmacokinetic properties

In studies with the 50 mg/ml 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 drug was widely distributed throughout the body. Longest 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

Dicyclanil has the potential to cause harmful effects on aquatic invertebrates and dung fly larvae.

Following use of this product, levels of dicyclanil potentially harmful to dung fly larvae have been shown to be excreted in faeces for approximately 4 weeks. Faeces from treated animals may temporarily reduce the abundance of dung fly larvae which may impact on dung degradation.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Methyl parahydroxybenzoate (E218)

Propyl parahydroxybenzoate
Butylated hydroxytoluene
Ponceau 4R
Polysorbate 20
Acrylic acid copolymer Disodium edetate
Distilled monoglycerides
Triglycerides, medium-chain Propylene glycol
Sodium hydroxide
Purified water

6.2 Incompatibilities

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

6.3 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

6.4 Special precautions for storage

Store in the original container.
Keep the container tightly closed, away from food, drink and animal feedstuffs.
Protect from direct sunlight.
Protect from frost

6.5 Nature and composition of immediate packaging

1 L, 2.5 L and 5 L white opaque polyethylene back pack containers filled with 0.8 L, 2.2 L and 5 L, respectively, and closed with a polypropylene screw cap. Not all pack sizes may be marketed.

6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.
Harmful to aquatic invertebrates.
Do not contaminate ponds or other waterways with product or empty containers.

7. MARKETING AUTHORISATION HOLDER

Elanco Europe Ltd
Lilly House
Priestley Road
Basingstoke
Hampshire
RG24 9NL

8. MARKETING AUTHORISATION NUMBER

Vm 00879/4003

9. DATE OF THE FIRST AUTHORISATION

21 October 2016

10. DATE OF REVISION OF THE TEXT

November 2018

A handwritten signature in black ink, consisting of several vertical strokes followed by a horizontal line and a long, sweeping curve.

Approved 19 November 2018