# ANNEX III

# LABELLING AND PACKAGE LEAFLET

# A. LABELLING

**PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE**
**POLYETHYLENE BACK PACK CONTAINER**

**1 litre container**

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

CLIK 50 mg/ml Pour-On Suspension

## 2. STATEMENT OF ACTIVE SUBSTANCES

Dicyclanil 50 mg/ml

## 3. PACKAGE SIZE

0.8 litres.

## 4. TARGET SPECIES

Sheep.

## 5. INDICATIONS

## 6. ROUTES OF ADMINISTRATION

Pour on.

## 7. WITHDRAWAL PERIODS

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

## 8. EXPIRY DATE

Exp. {mm/yyyy}
Once opened use within 1 year
Once opened use by….

## 9. SPECIAL STORAGE PRECAUTIONS

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

## 10. THE WORDS "READ THE PACKAGE LEAFLET BEFORE USE"

Read the package leaflet before use.

## 11. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

## 12. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

## 13. NAME OF THE MARKETING AUTHORISATION HOLDER

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

## 14. MARKETING AUTHORISATION NUMBERS

Vm 00879/3008

## 15. BATCH NUMBER

Lot {number}

# B. PACKAGE LEAFLET

# PACKAGE LEAFLET
# 1 litre container

## 1. Name of the veterinary medicinal product

CLIK 50 mg/ml Pour-On Suspension for Sheep.

## 2. Composition

**Each ml contains:**

**Active substance:**
Dicyclanil 50 mg
**Excipients:**

| | |
|---|---|
| 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 |

Pink coloured pour-on suspension.

## 3. Target species

Sheep.

## 4. Indications for use

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

## 5. 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.

## 6. Special warnings

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.

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.

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.

Interaction with other medicinal products and other forms of interaction:

None known.

Overdose:

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.

## 7. Adverse events

Target species: Sheep.

None known.

Reporting adverse events is important. It allows continuous safety monitoring of a product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system.

## 8. Dosage for each species, routes and method of administration

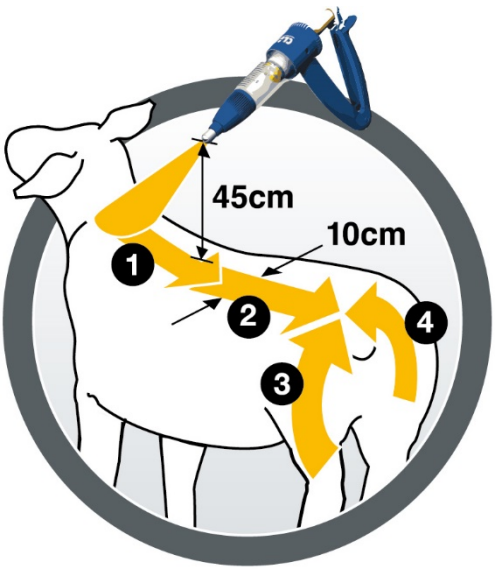
For external use only.
The veterinary medicinal product is applied according to the following recommendations:

| 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.

## 9. Advice on correct administration

Please refer to section on “Special Warnings” for further advice on administration.

## 10. Withdrawal periods

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

## 11. Special storage precautions

Keep out of the sight and reach of children.

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

Do not use this veterinary medicinal product after the expiry date which is stated on the label after Exp. The expiry date refers to the last day of that month.

Shelf life after first opening the container: 1 year.

## 12. Special precautions for disposal

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.
Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

## 13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

## 14. Marketing authorisation numbers and pack sizes

Vm 00879/3008

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.

## 15. Date on which the package leaflet was last revised

March 2023

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

## 16. Contact details

Marketing authorisation holder and contact details to report suspected adverse reactions:

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

PV. XXI@elancoah.com

Manufacturer responsible for batch release:

Elanco France S.A.S
26 Rue de la Chapelle
68330 Huningue
France

## 17. Other information

**PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE - COMBINED LABEL AND PACKAGE LEAFLET**

**POLYETHYLENE BACK PACK CONTAINER**

**2.5 and 5 litre pack sizes**

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

CLIK 50 mg/ml Pour-On Suspension for Sheep.

## 2. COMPOSITION

**Each ml contains**

**Active substance:**
Dicyclanil 50 mg

**Excipients:**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

Pink-colouredpour-on suspension.

## 3. PACKAGE SIZE

2.2 litres.
5 litres.

## 4. TARGET SPECIES

Sheep.

## 5. INDICATIONS FOR USE

**Indications for use**

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

## 6. CONTRAINDICATIONS

### 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.

## 7. SPECIAL WARNINGS

### Special warnings

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.

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.

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.

Interactions with other medicinal products and other forms of interaction:

None known.

Overdose:

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.

Special restrictions for use and special conditions for use:

Not applicable.

Major incompatibilities:

Not applicable.

## 8. ADVERSE EVENTS

**Adverse events**

Target species: Sheep.

None known.

Reporting adverse events is important. It allows continuous safety monitoring of a product. If you notice any side effects, even those not already listed on this label, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder using the contact details on this label, or via your national reporting system.

## 9. DOSAGE FOR EACH TARGET SPECIES, ROUTES AND METHOD OF ADMINISTRATION

**Dosage for each species, routes and method of administration**

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

| Body weight (kg) | Dose Volume (ml) |
|---|---|
| 10 – 20 | 20 |
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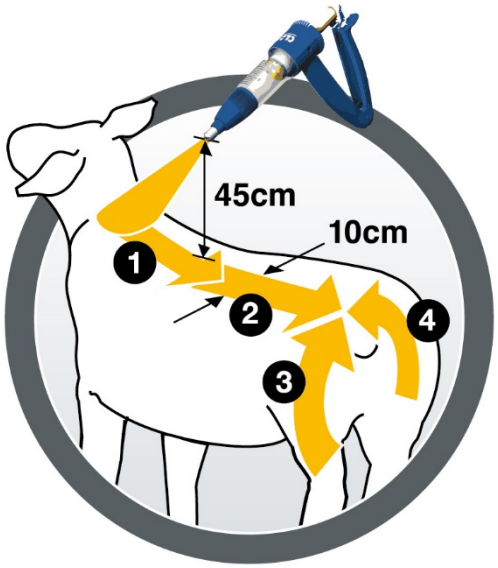
(Guide dose volumes correspond to 0.6 – 2 ml (30 – 100 mg dicyclanil) per kg bodyweight).

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.

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Do not shear sheep in the 3 months after treatment.

## 10. ADVICE ON CORRECT ADMINISTRATION

### Advice on correct administration

Please refer to section on “Special Warnings” for further advice on administration.

## 11. WITHDRAWAL PERIODS

### Withdrawal periods

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

## 12. SPECIAL STORAGE PRECAUTIONS

### Special storage precautions

Keep out of the sight and reach of children.

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

Do not use this veterinary medicinal product after the expiry date which is stated on the label after Exp. The expiry date refers to the last day of that month.
Shelf life after first opening the container: 1 year.

## 13. SPECIAL PRECAUTIONS FOR DISPOSAL

### Special precautions for disposal

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.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

## 14. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

### Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

## 15. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

Vm 00879/3008

**Pack sizes**

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.

## 16. DATE ON WHICH THE LABEL WAS LAST REVISED

**Date on which the label was last revised**

March 2023

Detailed information on this veterinary medicinal product is available in the Union Product Database.

## 17. CONTACT DETAILS

**Contact details**

Marketing authorisation holder and contact details to report suspected adverse reactions:

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

PV. XXI@elancoah.com

Manufacturer responsible for batch release:

Elanco France S.A.S
26 Rue de la Chapelle
68330 Huningue
France

## 18. OTHER INFORMATION

## 19. THE WORDS "FOR ANIMAL TREATMENT ONLY"

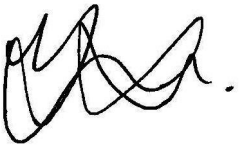
For animal treatment only.

## 20. EXPIRY DATE

Exp {mm/yyyy}
Once opened use within 1 year. Once opened use by….

## 21. BATCH NUMBER

Lot {number}



Approved: 17 April 2023