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 Extra 65 mg/ml Pour-On Suspension

2. STATEMENT OF ACTIVE SUBSTANCES

Dicyclanil 65 mg/ml

3. PACKAGE SIZE

1 litre (filled with 0.8 litres of product)

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, away from food, drink and animal feedstuffs.

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

14. MARKETING AUTHORISATION NUMBERS

Vm 00879/3010

15. BATCH NUMBER

Lot {number}

B. PACKAGE LEAFLET

PACKAGE LEAFLET
1 litre container

1. Name of the veterinary medicinal product

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

2. Composition

Each ml contains:

Active substance:
Dicyclanil 65 mg

Excipients:

Methyl parahydroxybenzoate (E218)	1.50 mg
Propyl parahydroxybenzoate	3.00 mg
Butylated hydroxytoluene	0.50 mg
Ponceau 4R	0.05 mg

Pink coloured suspension.

3. Target species

Sheep.

4. Indications for use

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

5. Contraindications

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

6. Special warnings

Special warnings:

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 for safe use in the target species:

Not applicable.

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.
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.

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.

Dicyclanil has the potential to cause harmful effects on aquatic invertebrates and dung fly larvae. Following use of this veterinary medicinal 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.

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

Major incompatibilities:

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

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.

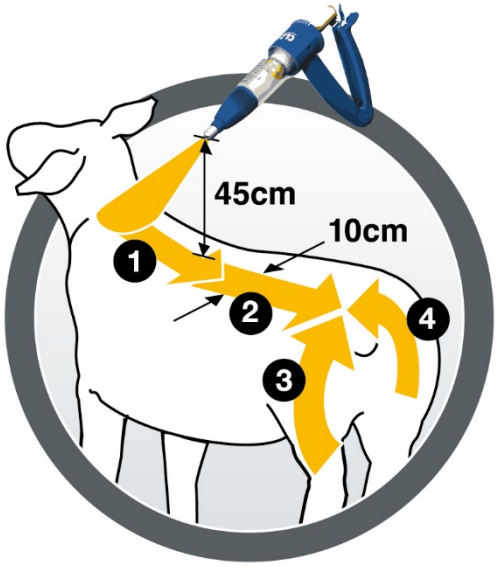
8. Dosage for each species, routes and method of administration

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

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 using a 4 stroke method as shown in the pictogram 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.

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, away from food, drink and animal feedstuffs.

Protect from direct sunlight.

Do not use this veterinary medicinal product after the expiry date 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.

Do not contaminate ponds or other waterways with product or 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.
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 00879/3010
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.

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:

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

2. COMPOSITION

Each ml contains:

Active substance:
Dicyclanil 65 mg

Excipients:

Methyl parahydroxybenzoate (E218)	1.50 mg
Propyl parahydroxybenzoate	3.00 mg
Butylated hydroxytoluene	0.50 mg
Ponceau 4R	0.05 mg

Pink coloured suspension.

3. PACKAGE SIZE

2.5 litres (filled with 2.2 litres of product)
5 litres (filled with 5 litres of product)

4. TARGET SPECIES

Sheep.

5. INDICATIONS FOR USE

Indications for use
Prevention of blowfly strike on sheep due to *Lucilia sericata* or *Wohlfahrtia magnifica*.

6. CONTRAINDICATIONS

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

7. SPECIAL WARNINGS

Special warnings

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 for safe use in the target species:
Not applicable.

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.
- 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.

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.

Dicyclanil has the potential to cause harmful effects on aquatic invertebrates and dung fly larvae.
Following use of this veterinary medicinal 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.

Pregnancy and lactation:
The safety of the product has not been established during pregnancy or lactation. Use only according to the benefit/risk assessment by the responsible veterinarian. Laboratory studies 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 4 times the recommended dose does not lead to any signs of local or systemic intolerance. No antidote is known.

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

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.

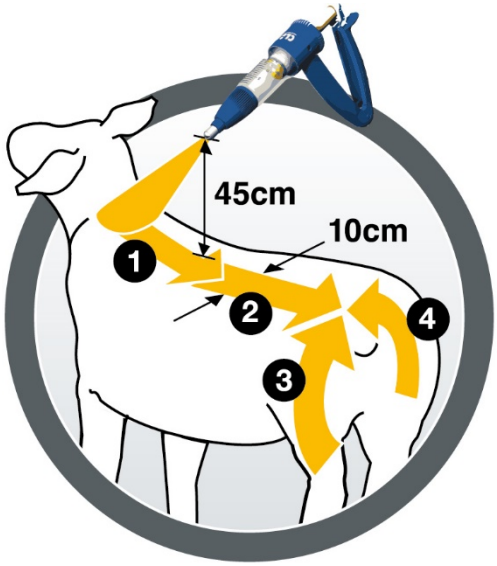
9. DOSAGE FOR EACH TARGET SPECIES, ROUTES AND METHOD OF ADMINISTRATION

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 using a 4 stroke method as shown in the pictogram 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.

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.

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

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.

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.

Harmful to aquatic and dung fauna.

Do not contaminate ponds or other waterways with product or 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.

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 00879/3010

Pack sizes
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.

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:

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}

Shelf life after first opening the immediate packaging: 1 year.

Once opened, use by…

21. BATCH NUMBER

Lot {number}

Approved 14 April 2023