

**PARTICULARS TO APPEAR ON IMMEDIATE PACKAGE – POLYETHYLENE BACK  
PACK CONTAINER – 1 LITRE**

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

CLiK Extra 65 mg/ml Pour-On Suspension

**2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES**

Each ml contains:

**Active substance:**

Dicyclanil 65 mg/ml

**Excipients:**

Methyl parahydroxybenzoate (E218) 1.50 mg

Propyl parahydroxybenzoate 3.00 mg

Butylated hydroxytoluene 0.50 mg

Ponceau 4R 0.05 mg

**3. PACKAGE SIZE**

1 litre (filled with 0.8 litres of product)

**4. TARGET SPECIES**

Sheep.

**5. INDICATION(S)**

**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 AND ADDRESS 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 00879/5013

## **15. BATCH NUMBER**

Lot {number}

## **16. SPECIAL WARNING(S), IF NECESSARY**

For external use only.

Special warnings for each 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.

Shake the container well before use.

Do not dilute with water.

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 use in cases of hypersensitivity to the active substance or to any of the excipients.

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.

Incompatibilities:

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

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 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.

#### **17. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY**

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.

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required. These measures should help protect the environment

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

#### **18. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE**

POM-VPS (To be supplied only on veterinary prescription).

## **PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:**

### **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

#### **Pour-On Suspension.**

Pink coloured suspension.

### **3. TARGET SPECIES**

Sheep

### **4. INDICATIONS FOR USE**

Prevention of blowfly strike on sheep due to *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 WARNING(S)**

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 shear sheep in the 3 months after treatment.

Do not apply during heavy rainfall, or when such conditions are expected. The resulting wash out may reduce the protection period.

#### Special precautions for the 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.

#### 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 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.

#### **For Animal Treatment Only**

**Keep out of sight and reach of children**

### **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, ROUTE(S) AND METHOD OF ADMINISTRATION**

For external use only.

The veterinary medicinal product is applied according to the following recommendations:

<b>Bodyweight (kg)</b>	<b>Dose Volume (ml)</b>
<b>10-20</b>	<b>20</b>
<b>21-30</b>	<b>24</b>
<b>31-50</b>	<b>30</b>
<b>&gt;50</b>	<b>36</b>

(Guide dose volumes correspond to 0.6–2 ml (39–130 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.

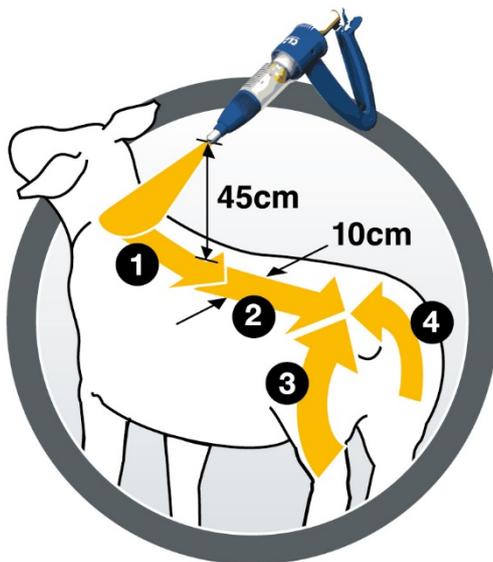
If animals are to be treated collectively rather than individually, they should be grouped according to their bodyweight and dosed accordingly, in order to avoid under- or overdosing.

Recommended for treatment in sheep 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 PERIOD(S)**

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 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.

When the container is opened for the first time, using the in-use shelf-life which is specified on this package leaflet, the date on which any product remaining in the container should be discarded should be determined. This discard date should be written in the space provided.

## **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.

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required. These measures should help protect the environment.

## **13. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS**

Veterinary medicinal product subject to prescription.

## **14. MARKETING AUTHORISATION NUMBERS AND PACK SIZES**

Vm 00879/5013

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

Find more product information by searching for the 'Product Information Database' or 'PID' on [www.gov.uk](http://www.gov.uk).

## 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

PV.GBR@elancoah.com

Manufacturer responsible for batch release

Argenta Dundee Limited

Kinnoull Road

Dunsinane Industrial Estate

Dundee

DD2 3XR

United Kingdom

Elanco France S.A.S

26 Rue de la Chapelle

68330 Huningue

France

## 17. OTHER INFORMATION

**MINIMUM PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGING WHERE  
THERE IS NO PACKAGE LEAFLET, I.e. Combined label and package leaflet  
{NATURE/TYPE}**

*[This template should only be used when all printed information is directly visible on the immediate container and cannot be used if a fold-out or concertina format is proposed.]*

**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

**Pour-On Suspension.**

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 shear sheep in the 3 months after treatment.

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.

#### 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 larve. Follow use of this veterinary medicinal product, levels of dicyclanil potentially harmful to dung fly larve 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.

#### **For Animal Treatment Only**

**Keep out of sight and reach of children**

## **8. ADVERSE REACTIONS**

### **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.

## 9. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

Dosage for each species, route(s) 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, body weight should be determined as accurately as possible; accuracy of the dosing device should be checked.

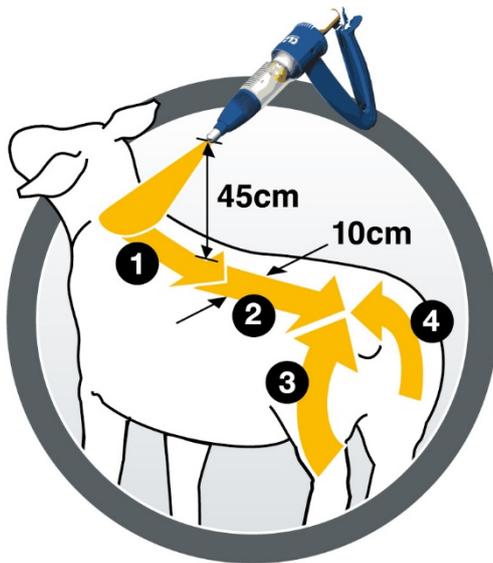
If animals are to be treated collectively rather than individually, they should be grouped according to their bodyweight and dosed accordingly, in order to avoid under- or overdosing.

Recommended for treatment in sheep 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 PERIOD

### Withdrawal periods

Meat and offal: 40 days

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

## 12. SPECIAL STORAGE PRECAUTIONS

### Special storage conditions

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.

When the container is opened for the first time, using the in-use shelf-life which is specified on this package leaflet, the date on which any product remaining in the container should be discarded should be determined. This discard date should be written in the space provided.

### **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.

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required. These measures should help protect the environment.

### **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 00879/5013

#### **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 of which the label was last revised**

March 2023

Find more product information by searching for the 'Product Information Database' or 'PID' on [www.gov.uk](http://www.gov.uk).

## 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.GBR@elancoah.com

### Manufacturer responsible for batch release

Argenta Dundee Limited  
Kinnoull Road  
Dunsinane Industrial Estate  
Dundee  
DD2 3XR  
United Kingdom

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}

## 22. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

Approved 14 April 2023

