PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE – POLYETHYLENE BACK PACK CONTAINER – 1 litre container

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

CLiKZiN 12.5 mg/ml Pour-On Suspension for Sheep

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each ml contains:

Active substance:
Dicyclanil 12.5 mg/ml

Excipients

Quinoline yellow (E104)	0.05 mg
Patent blue V (E131)	0.05 mg
Methyl parahydroxybenzoate (E218)	1.50 mg
Propyl parahydroxybenzoate	3.00 mg
Butylated hydroxytoluene (E321)	0.50 mg

3. PACKAGE SIZE

0.8 litres
2.2 litres
5 litres

4. TARGET SPECIES

Sheep

5. INDICATION(S)

6. ROUTES OF ADMINISTRATION

Pour-on

7. WITHDRAWAL PERIODS

Meat and offal: 7 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 NUMBER

Vm 00879/5012

15. BATCH NUMBER

Lot {number}

16. SPECIAL WARNING(S), IF NECESSARY

For external use only.

If you notice any serious effects or other effects not mentioned on this label, please inform your veterinary surgeon.

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.

User Warnings

- 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.

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

The safety of the veterinary medicinal product has not been established during pregnancy or lactation. Use only accordingly to the benefit/risk assessment by the responsible veterinarian. Laboratory studies have not produced any evidence of teratogenic, foetotoxic or maternotoxic effects.

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.

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

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.

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.

18. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE

POM-VPS (To be supplied on veterinary prescription)

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:
1 litre container

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

CLiKZiN 12.5 mg/ml Pour-On Suspension for Sheep

2. COMPOSITION

Each ml contains:

Active substance:
Dicyclanil 12.5 mg

Excipients:

Quinoline yellow (E104)	0.05 mg
Patent blue V (E131)	0.05 mg
Methyl parahydroxybenzoate (E218)	1.50 mg
Propyl parahydroxybenzoate	3.00 mg
Butylated hydroxytoluene (E321)	0.50 mg

Green coloured pour on suspension.

3. TARGET SPECIES

Sheep

4. INDICATIONS FOR USE

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

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:

None.

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.

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

Pregnancy and actation

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 20 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:

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

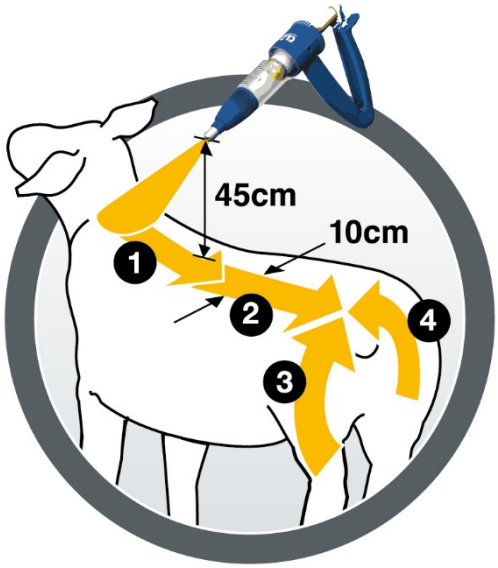
(Guide dose volumes correspond to 0.7–2 ml [7.5–25 mg dicyclanil] per kg bodyweight.)

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 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 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.

9. ADVICE ON CORRECT ADMINISTRATION

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

10. WITHDRAWAL PERIOD(S)

Meat and offal: 7 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 00879/5012

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

May 2023

Find more product information by searching for the 'Product Information Database' or 'PID' on 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
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

17. OTHER INFORMATION

MINIMUM PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGING WHERE THERE IS NO PACKAGE LEAFLET. Combined label and package leaflet POLYETHYLENE BACK PACK CONTAINER – 2.5 and 5 litre pack sizes

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

CLiKZiN 12.5 mg/ml Pour-On Suspension for Sheep

2. COMPOSITION

Each ml contains:

Active substance:
Dicyclanil 12.5 mg

Excipients

Quinoline yellow (E104)	0.05 mg
Patent blue V (E131)	0.05 mg
Methyl parahydroxybenzoate (E218)	1.50 mg
Propyl parahydroxybenzoate	3.00 mg
Butylated hydroxytoluene (E321)	0.50 mg

Green coloured pour-on suspension.

3. PACKAGE SIZE

0.8 litres
2.2 litres
5 litres

4. TARGET SPECIES

Sheep

5. INDICATIONS FOR USE

Indications for use

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

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:

None.

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.

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

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 20 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 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, 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**

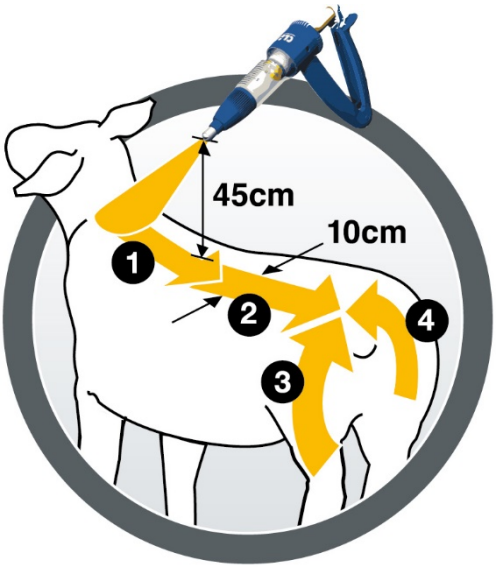
(Guide dose volumes correspond to 0.7–2 ml [7.5–25 mg dicyclanil] per kg bodyweight.)

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 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 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.

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: 7 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, 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.

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.

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 product 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.

POM-VPS

15. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

Vm 00879/5012

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

May 2023

Find more product information by searching for the ‘Product Information Database’ or ‘PID’ on 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

PV.GBR@elancoah.com

Manufacturer responsible for batch release (UK(GB)):
Argenta Dundee Limited
Kinnoull Road
Dunsinane Industrial Estate
Dundee
DD2 3XR
United Kingdom

Elanco 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 container: 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: 27 July 2023