PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

Polyethylene back pack container

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Dicyclanil Elanco 5% Pour-on Suspension.

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Dicyclanil, 5% (w/v).

3. PHARMACEUTICAL FORM

Pour-on Suspension.

4. PACKAGE SIZE

0.8, 2.2 or 5 litres.

5. TARGET SPECIES

Sheep.

6. INDICATION(S)

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

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Dicyclanil Elanco 5% Pour-on Suspension 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.)

The product must be applied with a manual or automatic dosing gun (e.g. Elanco Pour-on 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.

Dicyclanil Elanco 5% Pour-on Suspension 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.

Shake the container well before use.

8. WITHDRAWAL PERIOD

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

9. 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 precautions for use in animals
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 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.

The use of the product has harmful effects on dung flies.

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.

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 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 ingestion call for medical advice.
- 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 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.

10. EXPIRY DATE

<EXP {month/year}>
Once opened, discard after 12 months.

11. SPECIAL STORAGE CONDITIONS

Protect from direct sunlight.
Protect from frost.
Store in the original container.
Keep the container tightly closed.
Do not use after the expiry date stated on the label.

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product 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.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

For animal treatment only.

14. THE WORDS "KEEP OUT OF THE REACH AND SIGHT OF CHILDREN"

Keep out of the reach and sight of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

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

Manufacturer for batch release

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

GB and NI:
Elanco France S.A.S
26 Rue de la Chapelle
68330 Huningue
France

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

16. MARKETING AUTHORISATION NUMBER

Vm 00879/3000

17. MANUFACTURER'S BATCH NUMBER

<Batch> <Lot> <BN> {number}

B. PACKAGE LEAFLET

PACKAGE LEAFLET:

Dicyclanil Elanco 5% Pour-on Suspension

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Please refer to Annex IIIA, Point 15.

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Please refer to Annex IIIA, Points 1,3 and 5.

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

Please refer to Annex IIIA, Point 3.

4. INDICATION(S)

Please refer to Annex IIIA, Point 6.

5. CONTRAINDICATIONS

Please refer to Annex IIIA, Point 9.

6. ADVERSE REACTIONS

Please refer to Annex IIIA, Point 9.

7. TARGET SPECIES

Please refer to Annex IIIA, Point 5.

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

Please refer to Annex IIIA, Point 7.

9. ADVICE ON CORRECT ADMINISTRATION

Please refer to Annex IIIA, Point 7.

10. WITHDRAWAL PERIOD

Please refer to Annex IIIA, Point 8.

11. SPECIAL STORAGE PRECAUTIONS

Please refer to Annex IIIA, Point 11.

12. SPECIAL WARNING(S)

Please refer to Annex IIIA, Point 9.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Please refer to Annex IIIA, Point 13.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

Please refer to Annex IIIA, Point 15.

15. OTHER INFORMATION

Please refer to Annex IIIA, Point 15.

Approved 29 October 2021