PARTICULARS TO APPEAR ON THE OUTER PACKAGE
{1, 2.5 & 5 L cardboard box}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Cydectin 0.1% w/v Oral Solution

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each ml contains:
Active substance:

Moxidectin	1 mg

Excipients:

Benzyl alcohol (E1519)	40 mg
Butylated hydroxytoluene	2.5 mg
Disodium Edetate (E385)	0.27 mg

3. PACKAGE SIZE

1 L
2.5 L
5 L

4. TARGET SPECIES

Sheep

5. INDICATION(S)

6. ROUTES OF ADMINISTRATION

For oral use.

7. WITHDRAWAL PERIODS

Withdrawal period:
Meat and offal: 14 days.
Milk: 5 days.

8. EXPIRY DATE

Exp. {mm/yyyy}
Shelf life after first opening the immediate packaging: 6 months.
Once opened use by: "…/…/…"

9. SPECIAL STORAGE PRECAUTIONS

Do not store above 25ºC. Protect from light.

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

Zoetis UK Limited

14. MARKETING AUTHORISATION NUMBERS

Vm 42058/5133

15. BATCH NUMBER

Lot {number}:

16. SPECIAL WARNING(S), IF NECESSARY

Environmental risks have been identified for this product and special precautions apply. Read the package leaflet before use.

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

Disposal: read package leaflet.

18. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE

POM-VPS

Veterinary medicinal product subject to prescription.

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE {1, 2.5 & 5 L label}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Cydectin 0.1% w/v Oral Solution

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each ml contains:
Active substance:

Moxidectin	1 mg

Excipients:

Benzyl alcohol (E1519)	40 mg
Butylated hydroxytoluene	2.5 mg
Disodium Edetate (E385)	0.27 mg

1 L
2.5 L
5 L

3. TARGET SPECIES

Sheep

4. ROUTES OF ADMINISTRATION

For oral use.
Read the package leaflet before use.

5. WITHDRAWAL PERIODS

Withdrawal period:
Meat and offal: 14 days.
Milk: 5 days.

6. EXPIRY DATE

Exp. {mm/yyyy}
Shelf life after first opening the immediate packaging: 6 months.
Once opened use by: "…/…/…"

7. SPECIAL STORAGE PRECAUTIONS

Do not store above 25ºC. Protect from light.
Keep the bottle in the outer carton.

8. NAME OF THE MARKETING AUTHORISATION HOLDER

Zoetis UK Limited

9. BATCH NUMBER

Lot {number}:

10. SPECIAL WARNING(S), IF NECESSARY

Environmental risks have been identified for this product and special precautions apply. Read the package leaflet before use.

11. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: read package leaflet.

12. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE

For animal treatment only.

POM-VPS
Veterinary medicinal product subject to prescription.

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Cydectin 0.1% w/v Oral Solution for Sheep

2. COMPOSITION

Each ml contains:

Active substances:

Moxidectin	1 mg

Excipients:

Benzyl alcohol (E1519)	40 mg
Butylated Hydroxytoluene	2.50 mg
Disodium Edetate	0.27 mg

Pale yellow solution.

3. TARGET SPECIES

Sheep

4. INDICATIONS FOR USE

For the treatment and prevention of infections caused by:

- Adult and immature gastro-intestinal nematodes
  - *Haemonchus contortus* (including inhibited larvae)
  - *Ostertagia (Teladorsagia) circumcincta* (including inhibited larvae)
  - *Ostertagia (Teladorsagia) trifurcata*
  - *Trichostrongylus axei* (including inhibited larvae)
  - *Trichostrongylus colubriformis*
  - *Trichostrongylus vitrinus*
  - *Nematodirus battus*
  - *Nematodirus spathiger*
  - *Nematodirus filicolis* (adults only)
  - *Strongyloides papillosus* (larval stages only)

- *Cooperia curticei* (adults only)
- *Cooperia oncophora*
- *Oesophagostomum columbianum*
- *Oesophagostomum venulosum* (adults only)
- *Chabertia ovina*
- *Trichuris ovis* (adults only)

– Adult respiratory tract nematode

- *Dictyocaulus filaria*

– The veterinary medicinal product has a persistent effect in preventing reinfection:

- for 5 weeks *by Ostertagia (Teladorsagia) circumcincta* and *Haemonchus contortus*
- for 4 weeks *by Oesophagostomum columbianum*

5. CONTRAINDICATIONS

None.

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 veterinary medicinal product should be based on confirmation of the parasitic species and burden, or of the risk of infection based on its epidemiological features, for each flock.

Repeated use for an extended period, particularly when using the same class of substances, increases the risk of resistance development. Within a flock, maintenance of susceptible refugia is essential to reduce that risk. Systematically applied interval-based treatment and treatment of a whole flock should be avoided. Instead, if feasible, only selected individual animals or subgroups should be treated (targeted selective treatment). This should be combined with appropriate husbandry and pasture management measures. Guidance for each specific should be sought from the responsible veterinarian.

Multiple resistance of *Teladorsagia circumcincta* to moxidectin, levamisole, benzimidazole and ivermectin was reported throughout Europe. Moxidectin-resistant

Haemonchus contortus and *Trichostrongylus colubriformis* were also described. Therefore, the use of this veterinary medicinal product should take into account local information about susceptibility of the target parasites, where available. Additionally, use should be based on local history of treatments and recommendations on how to use the veterinary medicinal product under sustainable conditions to limit further selection for resistance to antiparasitic compounds. These precautions are especially important when moxidectin is being used to control resistant strains.

Resistance:
Clinical trials, after experimental and natural infection, have shown that the veterinary medicinal product is effective against certain benzimidazole resistant strains of:
. *Haemonchus contortus*
. *Ostertagia circumcincta*
. *Trichostrongylus colubriformis*
. *Cooperia curticei*

It is recommended to further investigate cases of suspected resistance, using an appropriate
diagnostic method (e.g. Faecal Egg Count Reduction Test). Where the results of the test(s) strongly suggest resistance to a particular anthelmintic, an anthelmintic belonging to another pharmacological class and having a different mode of action should be used. Confirmed resistance should be reported to the marketing authorisation holder or to the competent authorities.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
Avoid direct contact with skin and eyes.
Wash hands after use.
Do not smoke or eat when using this veterinary medicinal product.
Personal protective equipment consisting of impermeable rubber gloves should be worn when handling the veterinary medicinal product.

Special precautions for the protection of the environment:

Moxidectin fulfils the criteria for a (very) persistent, bioaccumulative and toxic (PBT) substance; therefore, exposure of the environment to moxidectin must be limited to the extent possible. Treatments should be administered only when necessary and should be based on faecal egg counts or evaluation of the risk of infestation at the animal and/or flock level.

Like other macrocyclic lactones, moxidectin has the potential to adversely affect non-target organisms, in particular aquatic organisms and dung fauna.

- Faeces containing moxidectin excreted onto pasture by treated animals may temporarily reduce the abundance of dung feeding organisms. Following treatment of sheep with the veterinary medicinal product, levels of moxidectin that are potentially toxic to dung fly species may be excreted over a period of 4 days

and may decrease dung fly abundance during that period. It has been established in laboratory tests that moxidectin may temporarily affect dung beetle reproduction; however, studies with incurred residues indicate no long-term effects. Nevertheless, in case of repeated treatments with moxidectin (as with veterinary medicinal products of the same anthelmintic class) it is advisable not to treat animals every time on the same pasture to allow dung fauna populations to recover.

- Moxidectin is inherently toxic to aquatic organisms including fish. The veterinary medicinal product should be used only according to the label instructions. Based on the excretion profile of moxidectin when administered as the oral formulation to sheep, treated animals should not have access to watercourses during the first 3 days after treatment.

Pregnancy and lactation:
The product has been shown to be safe for use in pregnant, lactating and breeding animals.

Interaction with other medicinal products and other forms of interaction:
The effects of GABA agonists are increased by moxidectin.

Overdose:
Symptoms generally do not occur at less than 5 times the recommended dose. They are manifested as transient salivation, depression, drowsiness and ataxia 8 to 12 hours post-treatment. Treatment is not generally necessary and recovery is generally complete within 24 to 48 hours. There is no specific antidote.

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

7. ADVERSE EVENTS

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 oral use.
The veterinary medicinal product should be given as a single oral drench of 1 ml/5 kg live bodyweight, equivalent to 200 µg moxidectin/kg live bodyweight, using any

standard drenching equipment. Underdosing could result in ineffective use and may favour resistance development.

To ensure a correct dosage, bodyweight should be determined as accurately as possible. If animals are to be treated collectively, reasonably homogeneous groups should be set up, and all animals of a group should be dosed at the rate corresponding to the heaviest one. Accuracy of the dosing device should be thoroughly checked.

9. ADVICE ON CORRECT ADMINISTRATION

None.

10. WITHDRAWAL PERIODS

Meat and offal: 14 days.
Milk: 5 days.

11. SPECIAL STORAGE PRECAUTIONS

Do not store above 25°C.
Protect from light.
Keep out of the sight and reach of children.
Do not use this veterinary 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: 6 months.
Keep the container in the outer carton.

12. SPECIAL PRECAUTIONS FOR DISPOSAL

Medicines should not be disposed of via wastewater.
Any unused veterinary medicinal product or waste material derived from such veterinary medicinal products should be disposed of in accordance with local requirements. The veterinary medicinal product should not enter water courses as moxidectin may be dangerous to fish and other aquatic organisms.
Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required. These measures should help to protect the environment.

13. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

14. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

Vm 42058/5133
The product is packaged in 1, 2.5 and 5L HDPE bottles with PP screw cap closure.
Not all pack sizes may be marketed.

15. PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

16. CONTACT DETAILS

Marketing authorisation holder and contact details to report suspected adverse reactions:
Zoetis UK Limited
1st Floor, Birchwood Building
Springfield Drive
Leatherhead
Surrey
KT22 7LP
Tel: +44 0345 300 8034

Manufacturer for the batch release:
Zoetis Manufacturing & Research Spain, S.L.
Ctra. Camprodón s/n "la Riba"
17813 Vall de Bianya
Girona
SPAIN

17. OTHER INFORMATION

Gavin Hall
Approved: 10 July 2024