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

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Cydectin TriclaMox 1 mg/ml + 50 mg/ml Oral Solution

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each ml contains:

Active substances

Moxidectin	1 mg
Triclabendazole	50 mg

Excipients

Benzyl alcohol (E1519)	40 mg
Butylhydroxytoluene (E321)	1 mg

3. PACKAGE SIZE

1 L
2.5 L
5 L

4. TARGET SPECIES

Sheep

5. INDICATION(S)

6. ROUTES OF ADMINISTRATION

Oral use.

7. WITHDRAWAL PERIODS

Withdrawal period:
Meat and offal: 31 days.
Milk: not authorised for use in ewes producing milk intended for human consumption including during the dry period. Do not use within 1 year prior to the first lambing in ewes intended to produce milk for human consumption.

8. EXPIRY DATE

Exp. {mm/yyyy}>
Once opened, use within 6 months.
Once opened, use by: …/…/…".

9. SPECIAL STORAGE PRECAUTIONS

Do not store above 25 °C.
Protect from light.
Do not freeze.
Keep the container in the outer carton.

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

Zoetis UK Limited
1st Floor, Birchwood Building
Springfield Drive
Leatherhead
Surrey
KT22 7LP

14. MARKETING AUTHORISATION NUMBERS

Vm 42058/5111

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
To be supplied only on veterinary prescription.

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

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Cydectin TriclaMox 1mg/ml + 50 mg/ml Oral Solution

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each ml contains:

Active substance:

Moxidectin	1 mg
Triclabendazole	50 mg

Excipients

Benzyl alcohol (E1519)	40 mg
Butylhydroxytoluene (E321)	1 mg

3. TARGET SPECIES

Sheep

4. ROUTES OF ADMINISTRATION

Oral use.
Read the package leaflet before use.

5. WITHDRAWAL PERIODS

Withdrawal period:
Meat and offal: 31 days.
Milk: not authorised for use in ewes producing milk intended for human consumption including during the dry period. Do not use within 1 year prior to the first lambing in ewes intended to produce milk for human consumption.

6. EXPIRY DATE

Exp. {mm/yyyy}:
Once opened, use within 6 months.

Once opened, use by: …/…/…".

7. SPECIAL STORAGE PRECAUTIONS

Do not store above 25 °C.
Protect from light.
Do not freeze.
Keep the container in the outer carton.

8. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Zoetis UK Limited
1st Floor, Birchwood Building
Springfield Drive
Leatherhead
Surrey
KT22 7LP

9. BATCH NUMBER

Lot {number}

10. PACKAGE SIZE

1 L
2.5 L
5 L

11. INDICATION(S)

12. SPECIAL WARNING(S), IF NECESSARY

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

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

Disposal: read the package leaflet.

14. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE

For animal treatment only.
POM-VPS
To be supplied only on veterinary prescription.

15. MARKETING AUTHORISATION NUMBER

Vm 42058/5111

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Cydectin TriclaMox 1 mg/ml + 50 mg/ml Oral Solution for sheep

2. COMPOSITION

Each ml contains:

Active substances

Moxidectin	1 mg
Triclabendazole	50 mg

Excipients

Benzyl alcohol (E1519)	40 mg
Butylhydroxytoluene (E321)	1 mg

Oral solution
A clear yellow to brown liquid

3. TARGET SPECIES

Sheep

4. INDICATIONS FOR USE

For the treatment of mixed nematode and fluke infections in sheep, caused by moxidectin and triclabendazole sensitive strains of:

Parasite	Treatment		
	Adult stage	**L4**	**Inhibited stages**
Gastro-intestinal nematodes:			
Haemonchus contortus	**X**	**X**	**X**
Teladorsagia circumcincta	**X**	**X**	**X**
Ostertagia trifurcata	**X**	**X**	
Trichostrongylus axei	**X**	**X**	**X**
Trichostrongylus colubriformis	**X**	**X**	
Trichostrongylus vitrinus	**X**	**X**	
Nematodirus battus	**X**	**X**	
Nematodirus spathiger	**X**	**X**	
Nematodirus filicolis	**X**		
Strongyloides papillosus		**X**	
Cooperia curticei	**X**		
Cooperia oncophora	**X**	**X**	
Oesophagostomum columbianum	**X**	**X**	
Oesophagostomum venulosum	**X**		
Chabertia ovina	**X**	**X**	
Trichuris ovis	**X**		
Respiratory tract nematode:			
Dictyocaulus filaria	**X**		
Liver fluke:	**Adult stage**	**Early Immature stages**	**Late Immature stages**
Fasciola hepatica	**X**	**X**	**X**

The product has a persistent efficacy and protects sheep against infection or re-infection with the following parasites for the period indicated:

Species	Protection period (days)
Teladorsagia circumcincta	35
Haemonchus contortus	35

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

5. CONTRAINDICATIONS

Do not use in cases of hypersensitivity to the active substance(s) or to any of the excipient(s).

6. SPECIAL WARNING(S)

Special warnings:
Care should be taken to avoid the following practices because they increase the risk of development of resistance and could ultimately result in ineffective therapy:

- Too frequent and repeated use of anthelmintics from the same class, over an extended period of time.
- Underdosing, which may be due to underestimation of body weight, misadministration of the product, or lack of calibration of the dosing device (if any).

Suspected clinical cases of resistance to anthelmintics should be further investigated using appropriate tests (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.

Resistance to macrocyclic lactones has been reported in *Teladorsagia* in sheep in a number of countries. In 2008, throughout Europe, moxidectin resistance is very rare. Resistance to triclabendazole has been reported in *Fasciola hepatica* in sheep in some European countries. Therefore the use of this product should be based on local (regional, farm) epidemiological information about susceptibility of parasites, local history of treatments and recommendations on how to use the 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.

This product should not be used for the treatment of single infections.

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

Interaction with other medicinal products and other forms of interaction:
In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

Overdose:
Signs of overdoses have not been seen at 3 and 5 times the recommended dose.
However, if they do occur they should be consistent with the mode of action of moxidectin and/or triclabendazole and would be manifested as transient salivation,

depression, drowsiness, ataxia and reduced food intake 8 to 12 hours post-treatment. Treatment is not generally necessary and recovery is generally complete within 1 to 5 days. There is no specific antidote.

Pregnancy:
This product is safe for use in breeding animals

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 herd 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 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 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 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.

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 or the local representative of 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 oral use.
The product should be given as a single oral drench of 1 ml/5 kg bodyweight, equivalent to 0.2 mg moxidectin/kg bodyweight and 10 mg triclabendazole/kg bodyweight, using any standard drenching equipment.

To ensure a correct dosage, 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 body weight and dosed accordingly, in order to avoid under- or overdosing.

9. ADVICE ON CORRECT ADMINISTRATION

None.

10. WITHDRAWAL PERIOD(S)

Meat and offal: 31 days.
Milk: not authorised for use in ewes producing milk intended for human consumption including during the dry period. Do not use within 1 year prior to the first lambing in ewes intended to produce milk for human consumption.

11. SPECIAL STORAGE PRECAUTIONS

Do not store above 25°C.
Protect from light.
Do not freeze.
Keep out of the sight and reach of children.
Do not use this veterinary medicinal product after the expiry date which is stated on the carton and label after “Exp”. The expiry date refers to the last day of that month.
Shelf-life after first opening the container: 6 months.
When the container is broached (opened) for the first time, using the in-use shelf-life which is specified on this package insert, the date on which any product remaining in the container should be discarded should be worked out. This discard date should be written in the space provided on the label.

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 for fish and other aquatic organisms. These measures should help to protect the environment.

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 42058/5111

1 L HDPE and 2.5L and 5L fluorinated HDPE bottles with polypropylene screw cap with induction seal.Not all pack sizes may be marketed.

15. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST REVISED

September 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:
Zoetis UK Limited
1st Floor, Birchwood Building
Springfield Drive
Leatherhead
Surrey
KT22 7LP

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

Approved 22 September 2023