

## **LABELLING AND PACKAGE LEAFLET**

## **A. LABELLING**

**PARTICULARS TO APPEAR ON THE OUTER PACKAGE**

Box for 1L HDPE container  
Box for 2.5L HDPE container  
Box for 5L HDPE container

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

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

**2. STATEMENT OF ACTIVE SUBSTANCES**

Each ml contains:

**Active substances**

Moxidectin 1 mg  
Triclabendazole 50 mg

**3. PHARMACEUTICAL FORM**

Oral solution

**4. PACKAGE SIZE**

1 L  
2.5 L  
5 L

**5. TARGET SPECIES**

Sheep

**6. INDICATION(S)**

*For OTC products:*

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
<b>Gastro-intestinal nematodes:</b>			
<i>Haemonchus contortus</i>	X	X	X
<i>Teladorsagia circumcincta</i>	X	X	X
<i>Ostertagia trifurcata</i>	X	X	
<i>Trichostrongylus axei</i>	X	X	X
<i>Trichostrongylus colubriformis</i>	X	X	
<i>Trichostrongylus vitrinus</i>	X	X	
<i>Nematodirus battus</i>	X	X	

<i>Nematodirus spathiger</i>	X	X	
<i>Nematodirus filicollis</i>	X		
<i>Strongyloides papillosus</i>		X	
<i>Cooperia curticei</i>	X		
<i>Cooperia oncophora</i>	X	X	
<i>Oesophagostomum columbianum</i>	X	X	
<i>Oesophagostomum venulosum</i>	X		
<i>Chabertia ovina</i>	X	X	
<i>Trichuris ovis</i>	X		
<b>Respiratory tract nematode:</b>			
<i>Dictyocaulus filaria</i>	X		
<b>Liver fluke:</b>	<b>Adult stage</b>	<b>Early Immature stages</b>	<b>Late Immature stages</b>
<i>Fasciola hepatica</i>	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)
<i>Teladorsagia circumcincta</i>	35
<i>Haemonchus contortus</i>	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*.

## 7. METHOD AND ROUTE(S) OF ADMINISTRATION

For oral use.

Read the package leaflet before use.

## 8. WITHDRAWAL PERIOD(S)

Meat and offal: 31 days.

Milk: not authorized 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.

**9. SPECIAL WARNING(S), IF NECESSARY**

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

**10. EXPIRY DATE**

EXP {month/year}>  
After first opening, use the product within 6 months.  
Once opened, use by: .../.../...”.

**11. SPECIAL STORAGE CONDITIONS**

Do not store above 25 °C.  
Protect from light.  
Do not freeze.

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

Disposal: read package leaflet .

**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 SIGHT AND REACH OF CHILDREN”**

Keep out of the sight and reach of children.

**15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER**

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

**16. MARKETING AUTHORISATION NUMBER**

Vm 42058/4030

**17. MANUFACTURER’S BATCH NUMBER**

Lot {number}

**PARTICULARS TO APPEAR ON IMMEDIATE PACKAGING UNITS**

LABEL 1L HDPE container  
LABEL 2.5 L HDPE container  
LABEL 5 L HDPE container

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

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

**2. STATEMENT OF ACTIVE SUBSTANCES**

Each ml contains:

**Active substance:**

Moxidectin	1 mg
Triclabendazole	50 mg

**3. PHARMACEUTICAL FORM**

Oral solution

**4. PACKAGE SIZE**

1 L  
2.5 L  
5 L

**5. TARGET SPECIES**

Sheep

**6. INDICATION(S)**

Read the package leaflet before use.

*For OTC products*

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

Read the package leaflet before use.

**7. METHOD AND ROUTE(S) OF ADMINISTRATION**

For oral use.

**8. WITHDRAWAL PERIOD(S)**

Meat and offal: 31 days.

Milk: not authorized 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.

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

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

#### **10. EXPIRY DATE**

EXP {month/year}:  
After first opening, use the product within 6 months.

Once opened, use by: .../.../...".

#### **11. SPECIAL STORAGE CONDITIONS**

Do not store above 25 °C.  
Protect from light.  
Do not freeze.

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

Disposal: read the package leaflet before use.

#### **13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE**

For animal treatment only.

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

Keep out of the sight and reach of children.

#### **15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER**

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1st Floor, Birchwood Building  
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KT22 7LP

#### **16. MARKETING AUTHORISATION NUMBER**

Vm 42058/4030

#### **17. MANUFACTURER'S BATCH NUMBER**

Lot {number}

## **B. PACKAGE LEAFLET**



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

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

**Marketing authorisation holder:**

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

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

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

**3. STATEMENT OF THE ACTIVE SUBSTANCES AND OTHER INGREDIENTS**

Oral solution  
A clear yellow to brown liquid

Each ml contains:

**Active substances**

Moxidectin	1 mg
Triclabendazole	50 mg

**Excipients**

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

**4. INDICATION(S)**

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
<b>Gastro-intestinal nematodes:</b>			
<i>Haemonchus contortus</i>	X	X	X
<i>Teladorsagia circumcincta</i>	X	X	X
<i>Ostertagia trifurcata</i>	X	X	
<i>Trichostrongylus axei</i>	X	X	X
<i>Trichostrongylus colubriformis</i>	X	X	
<i>Trichostrongylus vitrinus</i>	X	X	
<i>Nematodirus battus</i>	X	X	
<i>Nematodirus spathiger</i>	X	X	
<i>Nematodirus filicolis</i>	X		
<i>Strongyloides papillosus</i>		X	
<i>Cooperia curticei</i>	X		
<i>Cooperia oncophora</i>	X	X	
<i>Oesophagostomum columbianum</i>	X	X	
<i>Oesophagostomum venulosum</i>	X		
<i>Chabertia ovina</i>	X	X	
<i>Trichuris ovis</i>	X		
<b>Respiratory tract nematode:</b>			
<i>Dictyocaulus filaria</i>	X		
<b>Liver fluke:</b>	<b>Adult stage</b>	<b>Early Immature stages</b>	<b>Late Immature stages</b>
<i>Fasciola hepatica</i>	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)
<i>Teladorsagia circumcincta</i>	35
<i>Haemonchus contortus</i>	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. ADVERSE REACTIONS**

None known.

## **7. TARGET SPECIES**

Sheep

## **8. DOSAGE FOR EACH SPECIES, ROUTE 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 authorized 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 breached (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 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.

### **User warning:**

Avoid direct contact with skin and eyes.

Wash hands after use.

Do not smoke, drink or eat when using this product.

Wear impermeable rubber gloves during use.

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

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.

This product is safe for use in breeding animals

### Other precautions regarding impact on 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.

### **13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIAL, IF ANY**

Any unused veterinary medicinal product or waste material derived from such veterinary medicinal products should be disposed of in accordance with local requirements. Do not contaminate watercourses with the product s as this may be dangerous for 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.

### **14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED**

June 2021

### **15. OTHER INFORMATION**

The product is packaged in 1L, 2.5L and 5L HDPE containers.  
Not all pack sizes may be marketed.  
The product is safe for use in breeding animals.

Approved: 10/11/21

