ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Box for 0.5L HDPE container
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 5 mg/ml + 200 mg/ml Pour-on Solution

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:

Moxidectin	5 mg
Triclabendazole	200 mg

3. PACKAGE SIZE

0.5 L
1 L
2.5 L
5 L

4. TARGET SPECIES

Cattle.

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Pour-on use.

7. WITHDRAWAL PERIODS

Withdrawal periods:
Meat and offal: 143 days.
Milk: Do not use in cattle of any age intended to produce milk for human consumption.

Due to the significant likelihood of cross-contamination of non-treated animals with this product due to grooming (licking), treated animals should be housed separately from non-treated animals throughout the withdrawal period. Non-compliance with this recommendation may lead to residues violations in non-treated animals.

8. EXPIRY DATE

Exp. {mm/yyyy}
After first opening, use the product within 6 months.
Once opened, use by: "…/…/…".

9. SPECIAL STORAGE PRECAUTIONS

Do not store above 25°C.
Protect from light.
Do not freeze.
If accidentally frozen, shake vigorously before use.

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 NUMBER

Vm 42058/3012

15. BATCH NUMBER

Lot {number}:

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

LABEL 0.5L HDPE container
LABEL 1L HDPE container
LABEL 2.5L HDPE container
LABEL 5L HDPE container

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Cydectin TriclaMox 5 mg/ml + 200 mg/ml Pour-on Solution

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:

Moxidectin	5 mg
Triclabendazole	200 mg

0.5 L
1 L
2.5 L
5 L

3. TARGET SPECIES

Cattle

4. ROUTES OF ADMINISTRATION

Pour-on use.
Read the package leaflet before use.

5. WITHDRAWAL PERIODS

Withdrawal periods:
Meat and offal: 143 days.
Milk: Do not use in cattle of any age intended to produce milk for human consumption.

6. EXPIRY DATE

Exp. {mm/yyyy}
After first opening, use the product within 6 months.

Once opened, use by: "…/…/…".

7. SPECIAL STORAGE PRECAUTIONS

Do not store above 25°C.
Protect from light.
Do not freeze.
If accidentally frozen, shake vigorously before use.

8. NAME OF THE MARKETING AUTHORISATION HOLDER

Zoetis UK Limited

9. BATCH NUMBER

Lot {number}

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Cydectin TriclaMox 5 mg/ml + 200 mg/ml Pour-on Solution for cattle

2. Composition

Each ml contains:

Active substances

Moxidectin	5 mg
Triclabendazole	200 mg

Excipients

Butylhydroxytoluene (E321)	5 mg

Pour-on solution
A clear, amber liquid

3. Target species

Cattle.

4. Indications for use

Treatment of mixed trematode (fluke) and nematode infections and certain arthropod infestations caused by moxidectin and triclabendazole sensitive strains of:

Parasite	**Adult stage**		**Inhibited stages**
NEMATODES		**L4**	
Gastro-intestinal nematodes:			
Haemonchus placei	●	●	
Ostertagia ostertagi	●	●	●
Trichostrongylus axei	●	●	
Nematodirus helvetianus	●	●	
Cooperia oncophora	●	●	
Cooperia punctata	●		
Oesophagostomum radiatum	●		
Bunostomum phlebotomum	●		
Respiratory tract nematode:			
Dictyocaulus viviparus	●		
TREMATODES			
Liver fluke:		6 – 8 weeks immatures	
Fasciola hepatica	●	●	
ECTOPARASITES			
Linognathus vituli	●		
Bovicola bovis	●		

Solenopotes capillatus	●		

The product has a persistent effect in preventing re-infection by *Ostertagia ostertagi* and by *Dictyocaulus viviparus* for 5 weeks after a single dose.

5. Contraindications

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

6. Special warnings

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 moxidectin has been reported mainly in Cooperia oncophora in some European countries.. Resistance to other MLs in some strains of *Cooperia* spp. can imply concurrent resistance to Moxidectin. Resistance to triclabendazole has been reported in Fasciola hepatica in cattle in some European countries. Triclabendazole resistant F. hepatica hosted in sheep can be transferred to cattle grazing the same pasture. 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 limit further selection for resistance to anthelmintics.

It has been shown that rainfall immediately before or within 2 hours after treatment will not affect the efficacy of the product.

Special precautions for safe use in the target species:
This veterinary medicinal 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. The veterinary medicinal product may cause skin and eye irritation. Avoid direct contact with skin and eyes.
Personal protective equipment consisting of gloves, protective work clothing and safety glasses should be worn when handling the veterinary medicinal product. In

case of accidental splash onto the eye or the skin, wash with plenty of clean, running water immediately.
If irritation persists, seek medical advice immediately and show the package leaflet or the label to the physician.
Do not smoke, drink or eat while handling the product. Wash hands after use.

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 cattle with the product, levels of moxidectin that are potentially toxic to dung fly species may be excreted over a period of more than 2 weeks 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, field studies 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. This implies that when allowing moxidectin to enter water bodies, this may have a severe and lasting impact on aquatic life. To mitigate this risk, the product should be used only according to the label instructions. Based on the excretion profile of moxidectin when administered as the pour-on formulation, treated animals should not have access to watercourses during the first week after treatment.

Pregnancy and lactation:
The product is safe for use in pregnant and lactating animals.

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 5 times the recommended dose. However, if they do occur they should be consistent with the mode of action of moxidectin and would be manifested as transient salivation, depression, drowsiness and ataxia. Treatment is not generally necessary and recovery is generally complete within 24 to 48 hours. There is no specific antidote.

7. Adverse events

Cattle

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Application site irritation, Digestive tract disorders (such as diarrhoea), Hypersensitivity reaction, Neurological disorders (such as ataxia)

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, routes and method of administration

For external use only.
The product should be administered at a dose rate of 0.5 mg moxidectin/kg body weight and 20 mg triclabendazole/kg body weight (equivalent to 1 ml of solution for 10 kg) and as a single pour-on application.

9. Advice on correct administration

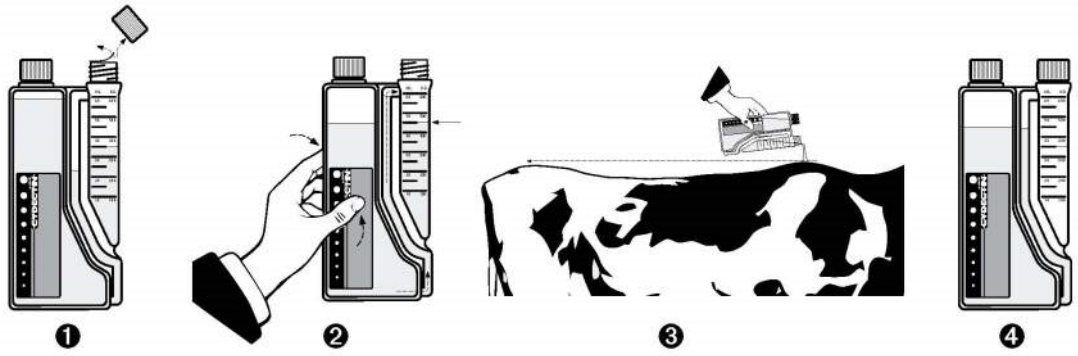
To be administered directly to the hair and skin along the midline of the back of the animal from the withers to the tail head.

Apply to clean healthy skin**.**
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 bodyweight and dosed accordingly, in order to avoid under- or overdosing.

Shake before use.

Directions for using the Squeeze-Pour System (500 ml and 1 litre bottles only):

Step 1: Remove screw cap from dispensing chamber only. Remove foil seal.
Step 2: Gently squeeze the bottle to fill the measuring chamber with the required amount of liquid.
Step 3: Pour the measured volume of fluid from the chamber onto the animal as directed. Repeat steps 2 and 3 for subsequent animals
Step 4: Reapply the screw cap to the dispensing chamber after use.



Directions for using a pour-on applicator (2.5 and 5 litre backpack):

Connect the pour-on applicator to the backpack as follows:
Attach the open end of the draw-off tubing to the cap with the stem.
Replace shipping cap with the cap that has the draw-off tubing. Tighten the draw-off cap.
Gently prime the pour-on applicator, checking for leaks.
Follow manufacturer's directions for correct use and care of.

10. Withdrawal periods

Meat and offal: 143 days.
Milk: Do not use in cattle of any age intended to produce milk for human consumption.

Due to the significant likelihood of cross-contamination of non-treated animals with this product due to grooming (licking), treated animals should be housed separately from non-treated animals throughout the withdrawal period. Non-compliance with this recommendation may lead to residues violations in non-treated animals.

11. Special storage precautions

Do not store above 25°C.
Protect from light.
Do not freeze.
If accidentally frozen, shake vigorously before use.
Keep out of the sight and reach of children.
Do not use after the expiry date stated on the carton and label after "Exp".
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 or household waste.
Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any applicable national collection systems. These measures should help to protect the environment. The veterinary medicinal product should not enter water courses as moxidectin may be dangerous for fish and other aquatic organisms.
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

The product is packaged in 0.5 L, 1 L, 2.5 L and 5 L HDPE containers.

Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

To be completed nationally.

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.
Carretera De Camprodon S/n°
La Vall de Bianya
17813 Girona
Spain

Local representatives and contact details to report suspected adverse reactions:

To be completed nationally.

17. Other information

To be completed in accordance with national requirements.

Approved 09 November 2023