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 0.5% w/v Pour-On

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:

Moxidectin 5.00 mg

3. PACKAGE SIZE

0.5 L
1 L
2.5 L
5 L

4. TARGET SPECIES

Cattle.

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

For pour-on use.

7. WITHDRAWAL PERIODS

Meat and offal: 14 days.
Milk: 6 days (144 hours).

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
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 NUMBERS

Vm 42058/3024

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 0.5% w/v Pour-On

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:

Moxidectin 5.00 mg

0.5 L
1L
2.5L
5 L

3. TARGET SPECIES

Cattle.

4. ROUTES OF ADMINISTRATION

–
For pour-on use. Read the package leaflet before use.

5. WITHDRAWAL PERIODS

Meat and offal: 14 days.
Milk: 6 days (144 hours).

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
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 0.5% w/v Pour-On for Cattle

2. Composition

Each ml contains:

Active Substance:
Moxidectin 5.00 mg

Excipients:
Butylated hydroxyanisole E320 0.10 mg
Tert butyl hydroquinone 0.03 mg

Pale yellow oily solution.

3. Target species

Cattle.

4. Indications for use

Infections of cattle with parasites sensitive to moxidectin.
For the treatment of infections caused by:

- Adult and larval gastro-intestinal nematodes:
  - *Haemonchus placei*
  - *Ostertagia ostertagi* (including inhibited larvae)
  - *Trichostrongylus axei*
  - *Nematodirus helvetianus*
  - *Cooperia oncophora*
  - *Cooperia punctata* (adults)
  - *Oesophagostomum radiatum* (adults)
  - *Bunostomum phlebotomum* (adults)

- Adult respiratory tract nematode:
  - *Dictyocaulus viviparus*

- Warbles (migrating larvae):
  - *Hypoderma bovis*
  - *Hypoderma lineatum*

- Lice:
  - *Linognathus vituli*
  - *Haematopinus eurysternus*
  - *Solenopotes capillatus*
  - *Bovicola bovis (Damalinia bovis)*

– Mange Mites:
  - *Sarcoptes scabiei*
  - *Psoroptes ovis*
  - *Chorioptes bovis*

- Horn Flies:
  - *Haematobia irritans*

  – Cydectin 0.5% w/v Pour-On for Cattle has a persistent effect in preventing against reinfection by:
  - *Ostertagia ostertagi* for 5 weeks
  - *Dictyocaulus viviparus* for 6 weeks.

5. Contraindications

Not to be used in other species as severe adverse reactions, including fatalities in dogs, may occur.

6. Special warnings

Special precautions for safe use in the target species:
For topical application only.

To avoid secondary reactions due to the death of *Hypoderma* larvae in the oesophagus or the spine, it is recommended to administer the veterinary medicinal product at the end of the period of fly activity and before the larvae reach their resting sites: consult the veterinarian to know the correct treatment period.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:

- Do not smoke, eat or drink while handling the veterinary medicinal product.
– Avoid direct contact with skin and eyes.
– Wash hands after use.
– Protective clothes and gloves are recommended when using the veterinary medicinal product.
– If splashed in the eye or on the skin, wash with plenty of clean, running water immediately.

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 veterinary medicinal 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 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. 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 veterinary medicinal 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, lactation and fertility:
Moxidectin has been shown to be safe for use in pregnant and lactating animals and breeding bulls.

Major incompatibilities:
Not to be mixed with other veterinary medicinal products before administration.

7. Adverse events

Cattle

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Application site reaction Neurological signs (such as ataxia (incoordination) and trembling) Lethargy

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: {national system details}.

8. Dosage for each species, routes and method of administration

The veterinary medicinal product should be administered at a dose rate of 500 µg moxidectin/kg body weight (1 ml for 10 kg) as a single topical application.

To be administered along the midline of the back of the animal from the withers to the tailhead.

Apply to clean healthy skin**.**

9. Advice on correct administration

None.

10. Withdrawal periods

Meat and offal: 14 days.
Milk: 6 days (144 hours).

11. Special storage precautions

Keep out of the sight and reach of children.

Do not store above 25 °C
Protect from light
If accidentally frozen, shake vigorously before use.
Do not use after the expiry date stated on the label after “Exp”.
Shelf-life after first opening the container: 6 months.
When the container is opened for the first time, using the in-use shelf-life which is specified on this package insert, the date on which any veterinary medicinal 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.

The veterinary medicinal product should not enter water courses as moxidectin may be dangerous for fish and other aquatic organisms.

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.
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 42058/3024

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. 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

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

Local representatives and contact details to report suspected adverse reactions:

17. Other information

To be completed in accordance with national requirements.

Gavin Hall

Approved: 06 July 2024