

LABELLING AND PACKAGE LEAFLET

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 for Cattle

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:

Active Substance:

Moxidectin 5.00 mg

Excipients:

Butylated hydroxyanisole E320 0.10 mg

Tert butyl hydroquinone 0.03 mg

3. PHARMACEUTICAL FORM

Pour-on solution

A pale yellow oily liquid

4. PACKAGE SIZE

0.5 L

1L

2.5L

5L

5. TARGET SPECIES

Cattle

6. INDICATION(S)

Infections of cattle with parasites sensitive to moxidectin.
Please read the leaflet for the full list of sensitive parasites.

For OTC products:

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

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For pour-on use. Read the package leaflet before use. The product should be administered at a dose rate of 0.5 mg moxidectin/kg body weight (1 ml for 10 kg) and as a single pour-on application.

Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

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

9. SPECIAL WARNING(S), IF NECESSARY

User warnings:

- Do not smoke, eat or drink while handling the product.
- Avoid direct contact with skin and eyes.
- Wash hands after use.

- Protective clothes and gloves are recommended when using the product.
- If splashed in the eye or on the skin, wash with plenty of clean, running water immediately.

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

If accidentally frozen, shake vigorously before use.

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, 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. The product can be toxic for fish and aquatic organisms.

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(S)

Vm 42058/5131

17. MANUFACTURER'S BATCH NUMBER
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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 for Cattle

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:

Active Substance:

Moxidectin 5.00 mg

Excipients:

Butylated hydroxyanisole E320 0.10 mg

Tert butyl hydroquinone 0.03 mg

3. PHARMACEUTICAL FORM

Pour-on solution

A pale yellow oily liquid

4. PACKAGE SIZE

0.5 L

1L

2.5L

5L

5. TARGET SPECIES

Cattle

6. INDICATION(S)

Infections of cattle with parasites sensitive to moxidectin.
Please read the leaflet for the full list of sensitive parasites.

For OTC products:

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

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For pour-on use. Read the package leaflet before use. The product should be administered at a dose rate of 0.5 mg moxidectin/kg body weight (1 ml for 10 kg) and as a single pour-on application.

Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

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

9. SPECIAL WARNING(S), IF NECESSARY

User warnings:

- Do not smoke, eat or drink while handling the product.

- Avoid direct contact with skin and eyes.
- Wash hands after use.
- Protective clothes and gloves are recommended when using the product.
- If splashed in the eye or on the skin, wash with plenty of clean, running water immediately.

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

If accidentally frozen, shake vigorously before use.

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

The product can be toxic for fish and aquatic organisms.

Avoid spillage directly into water courses.

Any unused product or waste material should be disposed of in accordance with national requirements.

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(S)

Vm 42058/5131

17. MANUFACTURER'S BATCH NUMBER
--

Lot {number}

B. PACKAGE LEAFLET

PACKAGE LEAFLET
Cydectin* 0.5% w/v Pour-On for Cattle

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 0.5% w/v Pour-On for Cattle

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

Each ml contains:

Active Substance:

Moxidectin 5.00 mg

Excipients:

Butylated hydroxyanisole E320 0.10 mg
Tert butyl hydroquinone 0.03 mg

4. INDICATION(S)

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. ADVERSE REACTIONS

Reactions at the site of application may occur after application in very rare occasions.

Neurological signs (including ataxia, trembling and lethargy) have been reported in very rare cases.

The frequency of adverse reactions is defined using the following convention:

- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

If you notice any serious effects, even those not already listed in this package leaflet,

or you think that the medicine has not worked, please inform your veterinary surgeon.

7. TARGET SPECIES

Cattle.

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

The 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 PERIOD(S)

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 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 WARNING(S)

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 product 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.

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 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.

Not to be mixed with other Veterinary Medicinal Products before administration.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, 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. The product can be toxic for fish and 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

January 2023

15. OTHER INFORMATION

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

Not all pack sizes may be marketed.

The product is safe for use in breeding animals.

Approved 19 January 2023

