LABELLING AND PACKAGE LEAFLET

Note, the following text is presented in order to highlight the changes resulting from the current variation(s). Harmonised labelling and package leaflet for this product have not yet been agreed by the Member States.

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Cardbox for 1 L, 2.5 L and 5 L

Sections 18 – 20 are only required in those markets that don't have a dedicated package leaflet

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Cydectin 0.1% w/v Oral Solution for Sheep
Moxidectin

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:

Moxidectin 1 mg

3. PHARMACEUTICAL FORM

Oral Solution

4. PACKAGE SIZE

5 L
2.5 L
1 L

5. TARGET SPECIES

Sheep

6. INDICATION(S)

Infections of sheep with parasites sensitive to moxidectin.

For the treatment and prevention of infections caused by:

– Adult and immature gastro-intestinal nematodes
. *Haemonchus contortus* (including inhibited larvae)
. *Ostertagia circumcincta* (including inhibited larvae)
. *Ostertagia trifurcata*
. *Trichostrongylus axei* (including inhibited larvae)
. *Trichostrongylus colubriformis*
. *Trichostrongylus vitrinus*
. *Nematodirus battus*
. *Nematodirus spathiger*
. *Nematodirus filicolis* (adults only)
. *Strongyloides papillosus* (larval stages only)
. *Cooperia curticei* (adults only)

. *Cooperia oncoaphora*
. *Oesophagostomum columbianum*
. *Oesophagostomum venulosym* (adults only)
. *Chabertia ovina*
. *Trichuris ovis* (adults only)

– - Adult respiratory tract nematode
. *Dictyocaulus filaria*

– The product has a persistent effect in preventing reinfection:
. for 5 weeks *by Ostertagia* circumcincta and *Haemonchus contortus*
. for 4 weeks *by Oesophagostomum columbianum*

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

7. METHOD AND ROUTE(S) OF ADMINISTRATION

200 µg moxidectin/kg live body (equivalent to 1ml/5 kg live bodyweight) as a single oral drench using any standard drenching equipment.
To ensure administration of a correct dosage, body weight should be determined as accurately as possible; accuracy of the dosing should be checked. Do not mix with other products.

8. WITHDRAWAL PERIOD(S)

Meat and offal: 14 days.
Milk: 5 days.

9. SPECIAL WARNING(S), IF NECESSARY

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; it has been reported in a single case involving a levamisole-, benzimidazole and ivermectin-resistant strain of Teladorsagia circumcincta. 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.

The effects of GABA agonists are increased by moxidectin.

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

If you notice any serious effects or other effects not mentioned on this label, please inform your veterinary surgeon.

Overdose

Symptoms generally do not occur at less than 5 times the recommended dose. They are manifested as transient salivation, depression, drowsiness and ataxia 8 to 12 hours post-treatment. Treatment is not generally necessary and recovery is generally complete within 24 to 48 hours. There is no specific antidote.

Contraindications

None

Special precautions to be taken by the person administering the medicinal products to animals

- Avoid direct contact with skin and eyes.
- Wash hands after use.
- Do not smoke or eat when using this product.
- Wear impermeable rubber gloves during use.

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:

- 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.

For the countries where a package leaflet is available in addition to outer label text, the text of section 9 is replaced by the following:

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

10. EXPIRY DATE

EXP {month/year} DD/MMM/YY
Shelf life after first opening the immediate packaging: 6 months.
Once opened use by

11. SPECIAL STORAGE CONDITIONS

Do not store above 25ºC. Protect from light.

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. Dangerous to fish and aquatic life.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required. These measures should help to protect the environment.

13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only.

To be supplied only on veterinary prescription.

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 42058/4024

17. MANUFACTURER'S BATCH NUMBER

Batch{number}:

18. 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

19. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

April 2022

20. OTHER INFORMATION

Pharmacodynamic properties
Moxidectin is a parasiticide active against a wide range of economically important internal and external parasites and is a second generation macrocyclic lactone of the milbemycin family. Its principal mode of action is interfering with neuromuscular transmission of the GABA (gamma amino butyric acid)-gated or glutamate-gated chloride channels.

Moxidectin stimulates the release of GABA and increases its binding to the postsynaptic receptors. The net effect is to open the chloride channels on the postsynaptic junction to allow the inflow of chloride ions and induce an irreversible resting state. This results in flaccid paralysis and eventual death of parasites exposed to the drug

Pharmacokinetic properties

22% of an oral dose of moxidectin is absorbed with maximum blood concentrations being achieved 9 hours post treatment. The drug is distributed throughout the body tissues but due to its lipophilicity the target tissue is fat where concentrations are 10 to 20 times higher than those found in other tissues. The depletion half life in fat is 23-28 days.

Moxidectin undergoes limited biotransformation by hydroxylation. The only significant route of excretion is the faeces.

Pack sizes

- Cardbox with 1, 2.5 and 5L HDPE containers with PP screw cap closure.

Not all pack sizes may be marketed.

PARTICULARS TO APPEAR ON IMMEDIATE PACKAGING

LABEL 1 L, 2.5 L, 5 L container

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Cydectin 0.1% w/v Oral Solution for Sheep
Moxidectin

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:

Moxidectin	1 mg

3. PHARMACEUTICAL FORM

Oral Solution

4. PACKAGE SIZE

5 L
2.5 L
1 L

5. TARGET SPECIES

Sheep

6. INDICATION(S)

Infections of sheep with parasites sensitive to moxidectin.

For the treatment and prevention of infections caused by:

- Adult and immature gastro-intestinal nematodes

. *Haemonchus contortus* (including inhibited larvae)
. *Ostertagia circumcincta* (including inhibited larvae)
. *Ostertagia trifurcata*
. *Trichostrongylus axei* (including inhibited larvae)
. *Trichostrongylus colubriformis*
. *Trichostrongylus vitrinus*
. *Nematodirus battus*
. *Nematodirus spathiger*
. *Nematodirus filicolis* (adults only)
. *Strongyloides papillosus* (larval stages only)
. *Cooperia curticei* (adults only)
. *Cooperia oncoaphora*
. *Oesophagostomum columbianum*
. *Oesophagostomum venulosym* (adults only)

. *Chabertia ovina*
. *Trichuris ovis* (adults only)

– - Adult respiratory tract nematode
. .*Dictyocaulus filaria*

– The product has a persistent effect in preventing reinfection:
. for 5 weeks *by Ostertagia* circumcincta and *Haemonchus contortus*
. for 4 weeks *by Oesophagostomum columbianum*

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

7. METHOD AND ROUTE(S) OF ADMINISTRATION

200 µg moxidectin/kg live body (equivalent to 1ml/5 kg live bodyweight) as a single oral drench using any standard drenching equipment.
To ensure administration of a correct dosage, body weight should be determined as accurately as possible; accuracy of the dosing should be checked. Do not mix with other products.

8. WITHDRAWAL PERIOD(S)

Meat and offal: 14 days.
Milk: 5 days.

9. SPECIAL WARNING(S), IF NECESSARY

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; it has been reported in a single case involving a levamisole-, benzimidazole and ivermectin-resistant strain of Teladorsagia circumcincta. 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.

The effects of GABA agonists are increased by moxidectin.

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

If you notice any serious effects or other effects not mentioned on this label, please inform your veterinary surgeon.

Overdose

Symptoms generally do not occur at less than 5 times the recommended dose. They are manifested as transient salivation, depression, drowsiness and ataxia 8 to 12 hours post-treatment. Treatment is not generally necessary and recovery is generally complete within 24 to 48 hours. There is no specific antidote.

Contraindications

None

Special precautions to be taken by the person administering the medicinal products to animals

- Avoid direct contact with skin and eyes.
- Wash hands after use.
- Do not smoke or eat when using this product.
- Wear impermeable rubber gloves during use.

Pharmacodynamic and pharmacokinetic properties

Moxidectin is a parasiticide active against a wide range of economically important internal and external parasites and is a second generation macrocyclic lactone of the milbemycin family. Its principal mode of action is interfering with neuromuscular transmission of the GABA (gamma amino butyric acid)-gated or glutamate-gated chloride channels.

Moxidectin stimulates the release of GABA and increases its binding to the postsynaptic receptors. The net effect is to open the chloride channels on the postsynaptic junction to allow the inflow of chloride ions and induce an irreversible resting state. This results in flaccid paralysis and eventual death of parasites exposed to the drug

22% of an oral dose of moxidectin is absorbed with maximum blood concentrations being achieved 9 hours post treatment. The drug is distributed throughout the body tissues but due to its lipophilicity the target tissue is fat where concentrations are 10 to 20 times higher than those found in other tissues. The depletion half life in fat is 23-28 days.

Moxidectin undergoes limited biotransformation by hydroxylation. The only significant route of excretion is the faeces.

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:

- 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.

For countries where package leaflet is available, the entire text in sec.9 is replaced by:

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

10. EXPIRY DATE

EXP {month/year} DD/MMM/YY
Shelf life after first opening the immediate packaging: 6 months.
Once opened use by

11. SPECIAL STORAGE CONDITIONS

Do not store above 25ºC. Protect from light.

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. Dangerous to fish and aquatic life.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required. These measures should help to protect the environment.

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

For animal treatment only.

To be supplied only on veterinary prescription.

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 42058/4024

17. MANUFACTURER'S BATCH NUMBER

Batch {number}:

B. PACKAGE LEAFLET

For illustrative purpose only: applicable only for countries where package leaflet is available.
In the others: all necessary information is presented on the outer packaging.

PACKAGE LEAFLET
CYDECTIN 0.1 % w/v 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 responsible for 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 0.1% w/v Oral Solution for Sheep
Moxidectin

3. STATEMENT OF THE ACTIVE SUBSTANCES AND OTHER INGREDIENTS

Oral solution
Pale yellow solution

Each ml contains:

Active substances
Moxidectin 1 mg

Excipients
Benzyl alcohol (E1519)
Butylated Hydroxy Toluene
Disodium Edetate

4. INDICATION(S)

For the treatment and prevention of infections caused by:

- Adult and immature gastro-intestinal nematodes
. *Haemonchus contortus* (including inhibited larvae)
. *Ostertagia circumcincta* (including inhibited larvae)
. *Ostertagia trifurcata*
. *Trichostrongylus axei* (including inhibited larvae)

. *Trichostrongylus colubriformis*
. *Trichostrongylus vitrinus*
. *Nematodirus battus*
. *Nematodirus spathiger*
. *Nematodirus filicolis* (adults only)
. *Strongyloides papillosus* (larval stages only)
. *Cooperia curticei* (adults only)
. *Cooperia oncoaphora*
. *Oesophagostomum columbianum*
. *Oesophagostomum venulosym* (adults only)
. *Chabertia ovina*
. *Trichuris ovis* (adults only)

– Adult respiratory tract nematode
. *Dictyocaulus filaria*

– Persistent activity
The product has a persistent effect in preventing reinfection:
. for 5 weeks *by Ostertagia* circumcincta and *Haemonchus contortus*
. for 4 weeks *by Oesophagostomum columbianum*

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

5. CONTRAINDICATIONS

None.

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 live bodyweight, equivalent to 200 µg moxidectin/kg live bodyweight, using any standard drenching equipment.

To ensure a correct dosage, bodyweight 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.
Do not mix with other products.

9. ADVICE ON CORRECT ADMINISTRATION

None.

10. WITHDRAWAL PERIOD(S)

Meat and offal: 14 days.
Milk: 5 days.

11. SPECIAL STORAGE PRECAUTIONS

Do not store above 25°C.
Protect from light.
Keep out of the sight and reach of children.
Do not use this veterinary product after the expiry date which is stated on the label after EXP. The expiry date refers to the last day of that month.Shelf-life after first opening the container: 6 months.
Keep the container in the outer carton.

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; it has been reported in a single case involving a levamisole-, benzimidazole and ivermectin-resistant strain of Teladorsagia circumcincta. 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.

If you notice any serious effects or other effects not mentioned on this label, please inform your veterinary surgeon.

Symptoms generally do not occur at less than 5 times the recommended dose. They are manifested as transient salivation, depression, drowsiness and ataxia 8 to 12 hours post-treatment. Treatment is not generally necessary and recovery is generally complete within 24 to 48 hours. There is no specific antidote.

The effects of GABA agonists are increased by moxidectin.

Not to be mixed with other Veterinary Medicinal Products before administration.
User warning
Avoid direct contact with skin and eyes.
Wash hands after use.
Do not smoke or eat when using this product.
Wear impermeable rubber gloves during use.

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. DANGEROUS to fish and aquatic life. 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

April 2022

15. OTHER INFORMATION

The product is packaged in 1, 2.5 and 5L HDPE bottles with PP screw cap closure. Not all pack sizes may be marketed.
The product has been shown to be safe for use in pregnant, lactating and breeding animals.

Approved 13 May 2022