ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

CARDBOX 50 ml or 200 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Cydectin 10% LA Solution for Injection for Cattle

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:
Moxidectin 100 mg

3. PACKAGE SIZE

50 ml
200 ml

4. TARGET SPECIES

Cattle.

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Subcutaneous use.

7. WITHDRAWAL PERIODS

Meat and offal: 108 days.
Milk: Not authorised for use in animals producing milk for human consumption. Do not use in pregnant animals which are intended to produce milk for human consumption within 80 days of expected parturition.
The withdrawal period is based solely on a single injection at the ear site of injection.

8. EXPIRY DATE

Exp. {mm/yyyy}
Shelf-life after first opening the container: 28 days.
Once broached/opened, use by: …/…/…"

9. SPECIAL STORAGE PRECAUTIONS

Do not store above 25ºC.
Keep the vial in the outer carton in order to protect from light.

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

14. MARKETING AUTHORISATION NUMBER

Vm 42058/3016

15. BATCH NUMBER

Lot {number}:

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

LABEL 200 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Cydectin 10% LA Solution for Injection

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:
Moxidectin 100 mg

3. TARGET SPECIES

Cattle.

4. ROUTES OF ADMINISTRATION

Subcutaneous use.

Read the package leaflet before use.

5. WITHDRAWAL PERIODS

Meat and offal: 108 days.
Milk: Not authorised for use in animals producing milk for human consumption. Do not use in pregnant animals which are intended to produce milk for human consumption within 80 days of expected parturition.

6. EXPIRY DATE

Exp. {mm/yyyy}
Shelf-life after first opening the container: 28 days.
Once broached/opened, use by: …/…/…"

7. SPECIAL STORAGE PRECAUTIONS

Do not store above 25ºC.
Keep the vial in the outer carton in order to protect from light.

8. NAME OF THE MARKETING AUTHORISATION HOLDER

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

9. BATCH NUMBER

Lot{number}:

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

VIAL LABEL 50 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Cydectin 10% LA

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Each ml contains:
Moxidectin 100 mg

3. BATCH NUMBER

Lot {number}:

4. EXPIRY DATE

Exp. {mm/yyyy}
Shelf-life after first opening the container: 28 days.
Once broached/opened, use by: …/…/…

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Cydectin 10% LA Solution for Injection for Cattle

2. Composition

Each ml contains:

Active substance:
Moxidectin 100 mg

Excipients:
Benzyl Alcohol 70 mg

Clear yellow solution for injection.

3. Target species

Cattle.

4. Indications for use

In cattle weighing from 100 to 500 kg body weight, treatment and prevention of mixed infestations by the following gastro-intestinal nematodes, respiratory nematodes and certain arthropod parasites:

– Adult and immature gastro-intestinal nematodes:
. *Haemonchus placei*
. *Haemonchus contortus*
. *Ostertagia ostertagi* (including inhibited larvae)
. *Trichostrongylus axei*
. *Trichostrongylus colubriformis*
. *Nematodirus helvetianus* (adults only)
. *Nematodirus spathiger*
. *Cooperia surnabada*
. *Cooperia oncophora*
. *Cooperia pectinata*
. *Cooperia punctata*
. *Oesophagostomum radiatum*
. *Bunostomum phlebotomum* (adults only)
. *Chabertia ovina* (adults only)
. *Trichuris spp.* (adults only)

– Adult and immature respiratory tract nematode
. *Dictyocaulus viviparus*

– Warble grubs (migrating larvae):

. Hypoderma bovis
. Hypoderma lineatum

– Lice
. Linognathus vituli
. Haematopinus eurysternus
. Solenopotes capillatus
. Bovicola bovis (aid in control)

– Mange mites
. Sarcoptes scabiei
. Psoroptes ovis
. Chorioptes bovis (aid in control)

The drug has a persistent action and protects cattle for certain duration against infection or re-infection with the following parasites for the period indicated:

Species	**Protection period (days)**
Dictyocaulus viviparus	120
Ostertagia ostertagi	120
Haemonchus placei	90
Oesophagostomum radiatum	150
Trichostrongylus axei	90
Linognathus vituli	133

The product is effective against Hypoderma larvae at the time of treatment but its persistent activity against Hypoderma has not been evaluated.
If the product is given before the end of the fly season complimentary treatment with a product effective against Hypoderma may be required.

Persistent efficacy periods have not been established for parasite species other than those included in the above list. Therefore, re-infection of animals on pasture contaminated by parasites other than these remains possible before the end of the 90 day minimum persistency period demonstrated for specific species.

5. Contraindications

Do not use in animals less than 100 kg bodyweight or greater than 500 kg.
Do not inject the product by intravascular route. Intravascular injection may result in ataxia, paralysis, convulsions, collapse and death. To prevent any intravascular injection, carefully follow the administration procedure described in item “Dosage for each species, routes and method of administration.”

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;

- Under-dosing which may 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.

Special precautions for safe use in the target species:
To prevent a possible anaphylactic type reaction, do not inject the product intravenously.
In order to prevent abscesses, a strict aseptic technique is recommended.
The veterinary medicinal product has been formulated specifically for subcutaneous injection in dorsal surface of the ear of cattle and must not be given by any other route of administration or to any other species.
To avoid possible secondary reactions by the death of Hypoderma larvae in the spine or the oesophagus of animals, it is recommended to administer a product effective against Hypoderma larvae after the end of fly activity and before the larvae reach their resting sites. Consult your veterinary surgeon on the correct timing of this treatment.
Immunity to nematodes depends on adequate exposure to infection. Although not normally the case, circumstances could occur in which anthelmintic control measures might increase the vulnerability of cattle to re-infection. Animals may be at risk towards the end of their first grazing season, particularly if the season is long, or in the following year if they move onto heavily contaminated pasture. In such instances, further control measures may be necessary.

Do not use in cattle less than 100 kg bodyweight or greater than 500 kg.

Reactions at the injection site have to be expected more frequently and severe depending on the injected volume.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
Avoid direct contact with skin and eyes.
Wash hands after use.
Do not smoke, drink or eat while handling the product.
Take care to avoid self-injection. Advice to Medical Practitioners in case of accidental self injection: Treat symptomatically.

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 4 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 injectable formulation, treated animals should not have access to watercourses during the first 10 days after treatment.

Pregnancy:
Can be used during pregnancy. However, note section on contraindications.

Interaction with other medicinal products and other forms of interaction:
The effects of GABA agonists are increased by moxidectin.

Overdose:
Systemic signs of overdoses are consistent with the mode of action of moxidectin. These signs are manifested as transient salivation, depression, drowsiness and ataxia 24 to 36 hours post-treatment. The systemic signs usually disappear within 36 to 72 hours without treatment. At doses >3 times the recommended dose divided on both ears, the systemic signs included recumbency, muscle tremor, ruminal tympany and dehydration, which were resolved after treatment with fluids. The systemic signs can last for a few days to ten days. There is no specific antidote.

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

7. Adverse events

Cattle:

Rare (1 to 10 animals / 10,000 animals treated):	Injection site swelling[1,2] Depression Ataxia (incoordination)
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Injection site abscess[2]

[1]immediate or delayed, may further develop into injection site abscesses, frequency tends to be higher in heavier animals
[2]generally disappear without treatment within 14 days after administration, may persist up to 5 weeks (<5% of cases) or longer (very rare occasions)

In case of hypersensitivity reactions, a symptomatic treatment should be applied.

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

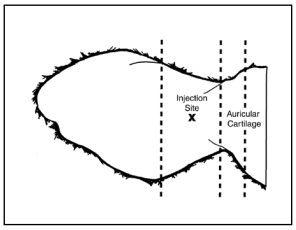
leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder or the local representative of the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system.

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

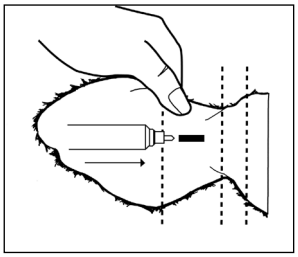
Subcutaneous use.
Dosage is 0.5 ml/50 kg bodyweight, equivalent to 1.0 mg moxidectin/kg bodyweight, given by a single subcutaneous injection in the ear using an 18 gauge, 25 – 40 mm hypodermic needle. The 50ml vial stoppers must not be broached more than 20 times. Use automatic syringe equipment for the 200 ml vial.
Shake well before use.
To ensure administration of a correct dosage, body weight should be determined as accurately as possible; accuracy of the dosing should be checked.
The injection should be given subcutaneously in the loose tissues on the dorsal surface of the ear, just distal to the distal edge of the auricular cartilage.
The dorsal (outer) surface of the ear should first be cleansed with antiseptic and allowed to briefly air dry. Palpate the edge of of the auricular cartilage closest to the head, on the dorsal (hairy) surface of the ear. From this landmark, taking care to avoid blood vessels (artery, vein), the needle should be inserted subcutaneously starting at a point approximately 3 to 3.5 cm distal to this edge (away from the head), and directed towards the base of the ear, and the needle advanced to the hub. At this point, gently aspirate the syringe to confirm that the needle is not in a blood vessel.
Upon injection, the resulting depot should reside just distal to the edge of the auricular cartilage.
Following administration, the needle is withdrawn from the skin as pressure is applied for several seconds with the thumb at the point of insertion.

Due to the long-lasting protection against *Dictyocaulus viviparus* and the stomach worms, *Ostertagia ostertagi* and *Haemonchus placei*, a single treatment with the formulation at turn-out helps control parasitic bronchitis (lungworm) and parasitic gastro-enteritis throughout the grazing season by reducing the build-up of infective larvae on pasture associated with these parasites. For best results the injection should be given to each calf of target weight to be grazed together immediately prior to being turned out to pasture. Animals should be set stocked throughout the grazing season or moved to a pasture which has not been grazed by other cattle earlier in the season.

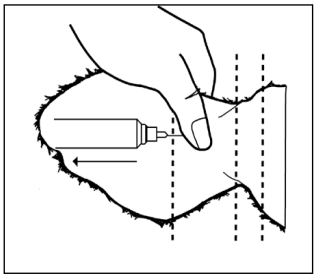
Diagram: Ear injection procedure



- The injection site is approximately 3.5 cm (1.5 inches) distal to the distal edge of the auricular cartilage.



- Use one hand to grasp and steady the ear.
- Inject subcutaneously using an 18 gauge x 1 inch needle.



- Inject contents. Depot should be just distal to the distal edge of the auricular cartilage.
- Apply pressure at the point of insertion as the needle is withdrawn from the skin to help seal the opening.

9. Advice on correct administration

To avoid possible anaphylactic type reaction, avoid intravenous administration.
In order to prevent abscesses, a strict aseptic technique is recommended. Cydectin 10% LA for Cattle has been formulated specifically for subcutaneous injection in dorsal surface of the ear of cattle and must not be given by any other route of administration or to any other species.

To avoid possible secondary reactions by the death of Hypoderma larvae in the spine or the oesophagus of animals, it is recommended to administer a product effective against Hypoderma larvae after the end of fly activity and before the larvae reach their resting sites. Consult your veterinary surgeon on the correct timing of this treatment.

10. Withdrawal periods

Meat and offal: 108 days.
Milk: Not authorised for use in animals producing milk for human consumption. Do not use in pregnant animals which are intended to produce milk for human consumption within 80 days of expected parturition.
The withdrawal period is based solely on a single injection at the ear site of injection.

11. Special storage precautions

Keep out of the sight and reach of children.
Do not store above 25 ºC. Keep the vial in the outer carton in order to protect from light.
Do not use after the expiry date stated on the label.
Shelf-life after first opening the container: 28 days.

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 42058/3016

Presentations to be sold:
- Box containing 1 vial of 50 ml size
- Box containing 1 vial of 200 ml size

Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

July 2023

“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 reaction>:
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 reaction>:
To be completed nationally.

17. Other information

Pharmacodynamics:
Moxidectin is an endectocide active against a wide range of internal and external parasites and is a second-generation macrocyclic lactone of the milbemycin family.

Moxidectin interacts with GABA receptors and chloride channels.
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.

Pharmacokinetics:
Moxidectin is absorbed following subcutaneous injection with maximum blood concentrations being achieved 24 to 48 hours post injection. The drug is distributed throughout the body tissues but due to its lipophilicity it is concentrated mainly in the fat. The depletion half-life in fat is 26 – 32 days.
Moxidectin undergoes limited biotransformation by hydroxylation in the body. The only significant route of excretion is the faeces.

To be completed in accordance with national requirements after conclusion of the MRP.

Approved 06 November 2023