1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Cydectin 0.1 % w/v Oral Solution for sheep

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance:
Moxidectin 1.00 mg

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Benzyl Alcohol (E1519)	40.00 mg
Butylated Hydroxytoluene	2.50 mg
Disodium Edetate (E385)	0.27 mg
Polysorbate 80	
Propylene glycol	
Dibasic sodium phosphate dodecahydrate	
Monobasic sodium phosphate dihydrate	
Purified water	
Phosphoric acid as a pH buffer	
Sodium hydroxide as a pH buffer	

Pale yellow solution

3. CLINICAL INFORMATION

3.1 Target species

Sheep.

3.2 Indications for use for each target species

For the treatment and prevention of infections caused by:

- Adult and immature gastro-intestinal nematodes
  - *Haemonchus contortus* (including inhibited larvae)
  - *Ostertagia (Teladorsagia) circumcincta* (including inhibited larvae)
  - *Ostertagia (Teladorsagia) 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 oncophora*
- *Oesophagostomum columbianum*
- *Oesophagostomum venulosum* (adults only)
- *Chabertia ovina*
- *Trichuris ovis* (adults only)

– Adult respiratory tract nematode
  - *Dictyocaulus filaria*

– The veterinary medicinal product has a persistent effect in preventing reinfection:
  - for 5 weeks *by Ostertagia (Teladorsagia)* circumcincta and *Haemonchus contortus*
  - for 4 weeks *by Oesophagostomum columbianum*

3.3 Contraindications

None.

3.4 Special warnings

Unnecessary use of antiparasitics or use deviating from the instructions given in the SPC may increase the resistance selection pressure and lead to reduced efficacy. The decision to use the veterinary medicinal product should be based on confirmation of the parasitic species and burden, or of the risk of
infection based on its epidemiological features, for each flock.

Repeated use for an extended period, particularly when using the same class of substances, increases the risk of resistance development. Within a flock, maintenance of susceptible refugia is essential to reduce that risk. Systematically applied interval-based treatment and treatment of a whole flock should be avoided. Instead, if feasible, only selected individual animals or subgroups should be treated (targeted selective treatment). This should be combined with appropriate husbandry and pasture management measures. Guidance for each specific flock should be sought from the responsible veterinarian.

Multiple resistance of *Teladorsagia circumcincta* to moxidectin, levamisole, benzimidazole and ivermectin was reported throughout Europe. Moxidectin-resistant *Haemonchus contortus* and *Trichostrongylus colubriformis* were also described. Therefore, the use of this veterinary medicinal product should take into account local information about susceptibility of the target parasites, where available. Additionally, use should be based on local history of treatments and recommendations on how to use the veterinary medicinal 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.

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

It is recommended to further investigate cases of suspected resistance, using an appropriate diagnostic method (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. Confirmed resistance should be reported to the marketing authorisation holder or to the competent authorities.

3.5 Special precautions for use

Special precautions for safe use in the target species:

Not applicable.

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 veterinary medicinal product.
- Personal protective equipment consisting of impermeable rubber gloves should be worn when handling the veterinary medicinal product.

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 flock 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 veterinary medicinal 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 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. The veterinary medicinal 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.

3.6 Adverse events

None known.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy, lactation and fertility:
The safety of moxidectin was established during pregnancy, lactation and in breeding bulls.

3.8 Interaction with other medicinal products and other forms of interaction

The effects of GABA agonists are increased by moxidectin.

3.9 Administration routes and dosage

Oral use.
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.
Underdosing could result in ineffective use and may favour resistance development.
To ensure administration of a correct dosage, body weight should be determined as accurately as possible. If animals are to be treated collectively, reasonably homogeneous groups should be set up, and all animals of a group should be dosed at the rate corresponding to the heaviest one.
Accuracy of the dosing should be thoroughly checked. Do not mix with other products.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

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.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance.

Not applicable.

3.12 Withdrawal periods

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

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code:

QP54AB02

4.2 Pharmacodynamics

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.

Resistance to moxidectin is mediated in part by membrane transporter P-glycoproteins, and cross resistance with other macrocyclic lactones is possible.

4.3 Pharmacokinetics

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.

Environmental properties

Moxidectin fulfils the criteria for a (very) persistent, bioaccumulative and toxic (PBT) substance. In particular, in acute and chronic toxicity studies with algae, crustaceans and fish, moxidectin showed toxicity to these organisms, yielding the following endpoints:

Organism		EC50	NOEC
Algae	*S. capricornutum*	>86.9 µg/l	86.9 µg/l
Crustaceans (Water fleas)	*Daphnia magna* (acute)	0.0302 µg/l	0.011 µg/l
	Daphnia magna (reproduction)	0.0031 µg/l	0.010 µg/l
Fish	*O. mykiss*	0.160 µg/l	Not determined
	L. macrochirus	0.620 µg/l	0.52 µg/l
	P. promelas (early life stages)	Not applicable	0.0032 µg/l
	Cyprinus carpio	0.11 µg/l	Not determined

EC_{50}: the concentration which results in 50% of the test species individuals being adversely affected, i.e. both mortality and sub-lethal effects.
NOEC: the concentration in the study at which no effects are observed.

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, all precautions for use and disposal must be adhered to.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

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

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years.
Shelf life after the first opening the immediate packaging: 6 months.

5.3 Special precautions for storage

Protect from light.
Do not store above 25 °C.

5.4 Nature and composition of immediate packaging

1, 2.5 and 5L HDPE bottles with PP screw cap closure.

Not all pack sizes may be marketed.

5.5 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products

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 national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Zoetis Belgium S.A

7. MARKETING AUTHORISATION NUMBER(S)

VPA10387/011/001

8. DATE OF FIRST AUTHORISATION

09/12/2013

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

07/02/2024

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).