1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Cydectin 1% w/v Injectable Solution for Sheep

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance:

Moxidectin 10.00 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 (E321)	2.50 mg
Disodium Edetate (E385)	0.27 mg
Polysorbate 80	
Sodium phosphate anhydrous	
Sodium acid phosphate monohydrate	
Propylene glycol	
Water for injections	

A clear to pale yellow solution

3. CLINICAL INFORMATION

3.1 Target species

Sheep.

3.2 Indications for use for each target species

Moxidectin is indicated for treatment of infections caused by moxidectin sensitive strains of:

– Gastro-intestinal nematodes:
- *Haemonchus contortus*
- *Ostertagia (Teladorsagia) circumcincta* (including inhibited larvae)
- *Trichostrongylus axei* (adults)
- *Trichostrongylus colubriformis* (adults and L3)
- *Nematodirus spathiger* (adults)
- *Cooperia curticei (macmasteri)* (adults)
- *Cooperia punctata* (adults)
- *Gaigeria pachyscelis* (L3)
- *Oesophagostomum columbianum* (L3)
- *Chabertia ovina* (adults)

– Respiratory tract nematode:
  - *Dictyocaulus filaria* (adults)

– Larvae of Diptera
  - Oestrus ovis : L1, L2, L3

– Mange mites:
  - Psoroptes ovis

– Moxidectin has a persistent effect of:
  - 5 weeks against *Ostertagia circumcincta*, *Haemonchus contortus*, *Psoroptes ovis*
  - 4 weeks against *Gaigeria pachyscelis* and *Oesophagostomum columbianum*
  - 2 weeks against *Trichostrongylus colubriformis*

Trials have shown that moxidectin is effective against strains of *Haemonchus contortus* resistant to benzimidazoles, ivermectin and doramectin.

3.3 Contraindications

Not to be used in animals with a history of previous vaccination against footrot. Such use may result in anaphylactic-type reactions, including dyspnoea, ataxia, depression, death and abortions.

3.4 Special warnings

None.

3.5 Special precautions for use

Special precautions for safe use in the target species:
Take care to accurately dose young lambs to avoid overdosing.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
Respect good veterinary practice.
Avoid direct contact with skin and eyes.
Wash hands after use.

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:

- 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 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, 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 injectable formulation to sheep, treated animals should not have access to watercourses during the first 11 days after treatment.

3.6 Adverse events

Sheep

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Hypersalivation[1,2] Ataxia[2] Depression[2], Drowsiness[2]

[1] Transient.
[2] Generally, no treatment is necessary; the symptoms resolve in 24 to 48 hours. There is no specific antidote.

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:
Laboratory studies (rat, rabbits) have shown that moxidectin has no teratogenic or embryotoxic effects at the therapeutic dose.
The veterinary medicinal product has been shown to be safe for use in pregnant ewes. Use in pregnant ewes possible.

3.8 Interaction with other medicinal products and other forms of interaction

Do not use in animals vaccinated against footrot. See also section 3.3.

3.9 Administration routes and dosage

Subcutaneous use.
200 µg moxidectin/kg live body (equivalent to 0.1 ml/5 kg live bodyweight) as a single subcutaneous injection.

- For mange, curative treatment necessitates two injections 10 days apart. Preventive treatment is a single injection.
- Administration should be done in front or behind the shoulder using a needle of 1.5 to 1.2 mm diameter and 1.5 cm length.

The use of multidosing equipment is recommended for the 200 and 500 ml bottles.

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

Symptoms of moxidectin overdoses are the same as those observed in very rare occasions at the recommended dose (see 3.6).

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: 82 days.
Milk: Not permitted for use in ewes producing milk for human consumption or industrial purposes or in pregnant or dry ewes for 60 days before lambing.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code:

QP 54 AB 02.

4.2 Pharmacodynamics

Moxidectin is a parasiticide active against a wide range of internal and external parasites and is a second-generation macrocyclic lactone of the milbemycin family. Its principal mode of action is interfering with GABA (gamma amino butyric acid) receptors involved in neuromuscular transmission.
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 veterinary medicinal product.

4.3 Pharmacokinetics

Moxidectin is rapidly and completely absorbed following subcutaneous injection with maximum blood concentrations being achieved about 8 hours post injection. The veterinary medicinal product is distributed throughout the body tissues but due to its lipophilicity fat concentrations are 10 to 20 times those in other tissues. The elimination half life in fat is about 7 days. Moxidectin undergoes partial biotransformation by hydroxylation in the body and 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: 36 months from date of manufacture.
Shelf life after first opening the immediate packaging: 28 days.

5.3 Special precautions for storage

Do not store above 25^{o}C.
Keep the vial in the outer carton in order to protect from light.

5.4 Nature and composition of immediate packaging

- Cardbox with 50ml high density polyethylene containers with bromobutyl rubber stoppers and aluminium caps.
- Cardbox with 200ml high density polyethylene containers with bromobutyl rubber stoppers and aluminium caps.
- Cardbox with 500ml high density polyethylene containers with bromobutyl rubber stoppers and aluminium caps.

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)

VPA10387/014/001

8. DATE OF FIRST AUTHORISATION

9 December 2013

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

2 January 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).