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

Benzyl Alcohol 40.00 mg
Butylated hydroxytoluene 2.50 mg
Disodium edetate 0.27 mg QSP 1.000 ml
For a full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Solution for Injection
A clear to pale yellow solution.

4 CLINICAL PARTICULARS

4.1 Target Species

Sheep

4.2 Indications for use, specifying the target species

In sheep: 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 nematodes:
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, 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.

4.3 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.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

Special precautions for use in animals
Take care to accurately dose young lambs to avoid overdosing

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

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

4.6 Adverse reactions (frequency and seriousness)

In very rare occasions, transient salivation, depression, drowsiness and ataxia may be reported in treated animals. No treatment is generally necessary. The symptoms resolve in 24 to 48 hours. There is no specific antidote.
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).

4.7 Use during pregnancy, lactation or lay

Laboratory studies (rat, rabbit) 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 is possible.

4.8 Interaction with other medicinal products and other forms of interaction

Do not use in animals vaccinated against footrot. See also 4.3.

4.9 Amounts to be administered and administration route

200 µg moxidectin/kg live body (equivalent to 0.1 ml/5 kg live body weight) as a single subcutaneous injection

- For mange, curative treatment necessitates two injections 10 days apart.

Preventative 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.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

Symptoms of moxidectin overdoses are the same as those observed in very rare occasions at the recommended dose (see 4.6).

4.11 Withdrawal period(s)

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.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group:endectocide (milbemycin family) ATC Vet: QP54AB02

5.1 Pharmacodynamic properties

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 anirreversible resting state. This results in flaccid paralysis and eventual death of parasites exposed to the drug.

5.2 Pharmacokinetic particulars

Moxidectin is rapidly and completely absorbed following subcutaneous injection with maximum blood concentrations being achieved about 8 hours post injection. The drug 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.

5.3 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		**EC_{50}**	**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.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Polysorbate 80
Sodium phosphate anhydrous
Sodium acid phosphate monohydrate
Benzyl alcohol
Butylated hydroxytoluene
Disodium edetate
Propylene glycol Water for injectable preparations

6.2 Major incompatibilities

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

6.3 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.

6.4 Special precautions for storage

Protect from light. Do not store above 25°C

6.5 Nature and composition of immediate packaging

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

Not all pack sizes may be marketed.

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

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 veterinary medicinal product can be toxic for fish and aquatic organisms.

7 MARKETING AUTHORISATION HOLDER

Zoetis Belgium S.A.
2nd Floor, Building 10
Cherrywood Business Park
Loughlinstown
Co Dublin
Ireland

8 MARKETING AUTHORISATION NUMBER(S)

VPA10387/014/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 28th August 1998
Date of last renewal: 27th August 2008

10 DATE OF REVISION OF THE TEXT

April 2018