Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Cydectin 1 % w/v Solution for injection for cattle

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance		
Moxidectin	10	mg
Excipients		
Benzyl Alcohol (E1519)	40	mg
Butylated Hydroxytoluene (E321)	2.5	mg
Disodium edetate (E 385)	0.27	ml

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Solution for injection. Yellow to pale yellow solution, free from suspended matter.

4 CLINICAL PARTICULARS

4.1 Target Species

Cattle.

4.2 Indications for use, specifying the target species

Moxidectin is an endectocide with activity against a wide range of internal and external parasites of cattle.

Cattle
Moxidectin is indicated for treatment and prevention of infections caused by:

- 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*
. Aid in the control of *Damalinia bovis*

- Mange mites
. *Sarcoptes scabiei*
. *Psoroptes ovis*
. Aid in the control of *Chorioptes bovis*

Moxidectin has a persistent effect against *Ostertagia*for 5 weeks and against *Dictyocaulus* for 6 weeks.

4.3 Contraindications

Do not use in lactating animals producing milk for human consumption or industrial purposes or within 60 days before parturition.

Do not use in horses.
Do not use in dogs.

4.4 Special warnings for each target species

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.

4.5 Special precautions for use

Special precautions for use in animals
Because of the particular susceptibility, it is not recommended to treat calves of less than 8 weeks. To avoid possible incidence of secondary reactions by the death of *Hypoderma*larvae in the spine or the oesophagus of animals, it is recommended to administer Cydectin 1% injectable after the end of fly activity and before the larvae reach their resting sites. The veterinary surgeon should give advice on the correct timing of treatment.

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 Practictioners in case of accidental self injection: Treat any specific signs symptomatically.

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 cattle with the product, levels of moxidectin that are potentially toxic to dung fly species may be excreted over a period 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. 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 10 days after treatment.

4.6 Adverse reactions (frequency and seriousness)

Drowsiness, depression, lethargy, apathy and weakness can be observed in very rare cases after treatment.
In very rare cases hypersensitivity reactions may occur, a symptomatic treatment is required.
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

Moxidectin has been shown to be safe for use in pregnant and lactating animals and breeding bulls.
However note 4.3. Contra-Indications.

4.8 Interaction with other medicinal products and other forms of interactions

The effects of GABA agonists are increased by moxidectin.

4.9 Amounts to be administered and administration route

1 ml/50 kg live bodyweight, equivalent to 0.2 mg moxidectin/kg live bodyweight given subcutaneously in front of or behind the shoulder using a 16-18 gauge (1.5 - 1.2 mm) 1/2 inch (1.5 cm) needle.

The use of a multidose equipment with a draw off needle is recommended for 200 ml and 500 ml packaging.

To ensure administration of a correct dosage, body weight should be determined as accurately as possible; accuracy of the dosing should be checked.

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

Symptoms of overdoses are consistent with the mode of action of moxidectin and generally do not occur at less than 3 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.

4.11 Withdrawal period(s)

Meat and offal: 65 days.
Milk: Not permitted for use in cattle producing milk for human consumption or industrial purposes or within 60 days before parturition.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Moxidectin, ATC vet code: QP 54 AB 02

5.1 Pharmacodynamic properties

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 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.
There is no evidence that moxidectin has any other pharmacological effect on any mammalian organ or tissue. The only toxic effects seen in toxicology or use animal safety tests are entirely consistent with its neuromuscular transmission mode of action.

5.2 Pharmacokinetic particulars

Moxidectin is rapidly and completely absorbed following subcutaneous injection with maximum blood concentrations being achieved 8-12 hours post injection. The drug is distributed throughout the body tissues but due to its lipophilicity the target tissue is fat where concentrations are 10 - 20 times those of in other tissues. The depletion half life in fat is 23-28 days.

Moxidectin undergoes limited biotransformation by hydroxylation in the body. 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

Benzyl alcohol (E1519)
Butylated hydroxytoluene (E321)
Disodium edetate (E 385)
Polysorbate 80
Propylene glycol
Sodium phosphate dibasic
Sodium phosphate monobasic
Phosphoric acid and/or Sodium hydroxide
Water for injection

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.
Shelf life after first opening the immediate packaging: 6 months.

6.4 Special precautions for storage

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

6.5 Nature and composition of immediate packaging

High density polyethylene containers of 50, 200 and 500 ml content sealed with bromobutyl stoppers.

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 product can be toxic for fish and other 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)

VPA10387/013/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 6th March 1995
Date of last renewal: 17th October 2009

10 DATE OF REVISION OF THE TEXT

September 2018