SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Cydectin* 0.5% w/v Pour-On for Cattle

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Substance:

Moxidectin	5.00 mg

Excipients:

Butylated hydroxyanisole E320	0.10 mg
Tert butyl hydroquinone	0.03 mg
	q.s. to 1. ml

For full list of excipients, see 6.1.

3. PHARMACEUTICAL FORM

Pour-on solution.
Pale yellow oily solution.

4. CLINICAL PARTICULARS

4.1 Target Species

Cattle

4.2 Indications for use specifying the target species

Infections of cattle with parasites sensitive to moxidectin.
For the treatment of infections caused by:

– Adult and larval gastro-intestinal nematodes:
. *Haemonchus placei*
. *Ostertagia ostertagi* (including inhibited larvae)
. *Trichostrongylus axei*
. *Nematodirus helvetianus*
. *Cooperia oncophora*
. *Cooperia punctata* (adults)
. *Oesophagostomum radiatum* (adults)
. *Bunostomum phlebotomum* (adults)

– Adult respiratory tract nematode
. *Dictyocaulus viviparus*

– Warbles (migrating larvae)
. *Hypoderma bovis*
. *Hypoderma lineatum*
– Lice
. *Linognathus vituli*
. *Haematopinus eurysternus*
. *Solenopotes capillatus*
. *Bovicola bovis (Damalinia bovis)*

– Mange Mites
. *Sarcoptes scabiei*
. *Psoroptes ovis*
. *Chorioptes bovis*

- Horn Flies
. *Haematobia irritans*

– Cydectin 0.5% w/v Pour-On for Cattle has a persistent effect in preventing against reinfection by:
. *Ostertagia ostertagi* for 5 weeks
. *Dictyocaulus viviparus* for 6 weeks.

4.3 Contraindications

None known.
See Section 4.11.

4.4 Special warnings for each target species

None

4.5 Special precautions for use

Special precautions for use in animals

For topical application only.
All animals in a group should be treated.

To avoid secondary reactions due to the death of *Hypoderma* larvae in the oesophagus or the spine, it is recommended to administer the productat the end of the period of fly activity and before the larvae reach their resting sites: consult the veterinarian to know the correct treatment period.

Special precautions to be taken by the person administering the veterinary medicinal product to animals

– Do not smoke, eat or drink while handling the product.
– Avoid direct contact with skin and eyes.
– Wash hands after use.
– Protective clothes and gloves are recommended when using the product.

– If splashed in the eye or on the skin, wash with plenty of clean, running water immediately.

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 2 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 pour-on formulation, treated animals should not have access to watercourses during the first week after treatment.

4.6 Adverse reactions (frequency and seriousness)

Reactions at the site of application may occur after application in very rare occasions.

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.
See Section 4.11.

4.8 Interactions with other medicinal products and other forms of interaction

None known.

4.9 Amounts to be administered and administration route

500 µg moxidectin/kg body weight (1 ml for 10 kg) as a single topical application.

To be administered along the midline of the back of the animal from the withers to the tailhead.

Apply to clean healthy skin.

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

No symptoms of overdose have been observed with the product given at ten times the recommended dose.
They are manifested as transient salivation, depression, drowsiness and ataxia. There is no specific antidote.

4.11 Withdrawal period(s)

Meat and offal: 14 days.
Milk: 6 days (144 hours).

5. PHARMACOLOGICAL PROPERTIES

ATC Vet Code: QP54AB02
Therapeutic group: endectocide (milbemycin family)

5.1 Pharmacodynamic properties

Moxidectin is a parasiticide active against a wide range of important internal and external parasites. It is a second generation macrocyclic lactone of the milbemycin family. Its principal mode of action is interference with the GABA (gamma amino butyric acid) receptors involved with 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 drug.

5.2 Pharmacokinetic particulars

Following pour-on application, the drug is distributed throughout the body tissues (except muscle) but due to its lipophilicity the concentrations in fat are 5-15 times those in other tissues.
Moxidectin undergoes partial biotransformation by hydroxylation in the body and the only significant route of excretion is the faeces, where the parent compound accounts for approximately 50%.

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		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.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Aromatic Solvent
Myristal Propoxylate Propionic Ester
Polybutene Polymer
Propylene Glycol
Butylated hydroxyanisole (E320)
Tertiary Butylhydroquinone
Citric Acid Monohydrate (E330)
Fractionated coconut oil

6.2 Major incompatibilities

Not to be mixed with other Veterinary Medicinal Products before administration.

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 24 months.
Shelf life after first opening the immediate packaging: 6 months.

6.4 Special precautions for storage

Keep the container in the outer carton to protect from light.

Do not store above 25°C.
If accidentally frozen, shake vigorously before use.

6.5 Nature and composition of immediate packaging

500, 1000, 2500 and 5000 ml fluorinated high-density polyethylene containers.

Not all pack sizes may be marketed.

6.6 Special precautions for the disposal of unused veterinary medicinal product 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 aquatic organisms.

7. MARKETING AUTHORISATION HOLDER

Zoetis UK Limited
1st Floor, Birchwood Building
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KT22 7LP

8. MARKETING AUTHORISATION NUMBER

Vm 42058/4025

9. DATE OF FIRST AUTHORISATION

10 January 1997

10. DATE OF REVISION OF THE TEXT

January 2020

Approved 08 January 2020