1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Cydectin 0.5% Pour-On Solution for Cattle

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:
Active substances:

Moxidectin 5,00 mg

Excipients:

Qualitative composition of excipients and other constituents	Quantitative composition
Solvent naphta light aromatic	
Polyoxypropylene (PPG-2) myristyl ether propionate	
Polybutene	
Mono- and diglycerides of fatty acids	
Propylene glycol	
Corn oil	
Butylated hydroxyanisole (E320)	0,10 mg
Tert-butyl hydroquinone (E319)	0,03 mg
Citric acid monohydrate	
Butylated hydroxytoluene (E321)	< 0,03 mg
Medium-chain triglycerides	

Pale yellow oily solution.

3. CLINICAL INFORMATION

3.1 Target species

Cattle.

3.2 Indications for use for each 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.

3.3 Contraindications

Not to be used in other species as severe adverse reactions, including fatalities in dogs, may occur.
See Section 3.12.

3.4 Special warnings

None.

3.5 Special precautions for use

Special precautions for safe use in the target species:
For topical application only.

To avoid secondary reactions due to the death of *Hypoderma* larvae in the oesophagus or the spine, it is recommended to administer the veterinary medicinal product at 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:
The veterinary product may cause skin and eye irritation. Avoid direct contact with skin and eyes. Do not smoke, drink or eat while handling the product. Wash hands after use.
Personal protective equipment consisting of gloves, protective work clothing and safety glasses should be worn when handling the veterinary medicinal product. If spillage onto clothing occurs, remove any contaminated clothing immediately and wash exposed skin with soap and water.
In case of accidental splash onto the eye or skin, wash with plenty of clean, running water immediately. If irritation persists, seek medical advice immediately and show the package leaflet or the label to the physician.

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

3.6 Adverse events

Cattle

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Application site reaction Neurological signs (such as ataxia and trembling) Lethargy

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. See Section 3.12.

3.8 Interaction with other medicinal products and other forms of interaction

None known.

3.9 Administration routes and dosage

Pour-on use.
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.

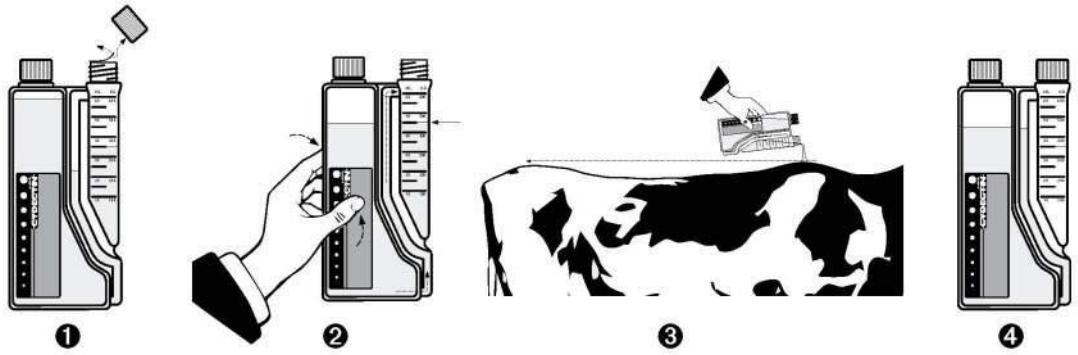
Apply to clean healthy skin.

To ensure a correct dosage, body weight should be determined as accurately as possible. Accuracy of the dosing device should be checked. If animals are to be treated collectively rather than individually,

they should be grouped according to their body weight and dosed accordingly, in order to avoid under- or overdosing.
Shake before use.

<u>Directions for using the Squeeze-Pour System</u> (500 ml and 1 litre bottles only):

Step 1: Remove screw cap from dispensing chamber only. Remove foil seal.
Step 2: Gently squeeze the bottle to fill the measuring chamber with the required amount of liquid.
Step 3: Pour the measured volume of fluid from the chamber onto the animal as directed. Repeat steps 2 and 3 for subsequent animals
Step 4: Reapply the screw cap to the dispensing chamber after use.



<u>Directions for using a pour-on applicator (2.5 and 5 litre backpack):</u>

Connect the pour-on applicator to the backpack as follows:
Attach the open end of the draw-off tubing to the cap with the stem.
Replace shipping cap with the cap that has the draw-off tubing. Tighten the draw-off cap.
Gently prime the pour-on applicator, checking for leaks.
Follow manufacturer's directions for correct use and care of equipment.

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

No symptoms of overdose have been observed with the veterinary medicinal product given at ten times the recommended dose.
They are manifested as transient salivation, depression, drowsiness and ataxia. 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: 6 days (144 hours).

4. PHARMACOLOGICALINFORMATION

4.1 ATCvet code : QP54AB02

4.2 Pharmacodynamics

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.

4.3 Pharmacokinetics

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%.

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 first opening the immediate packaging: 6 months.

5.3 Special precautions for storage

Keep the container in the outer carton in order to protect from light.
Do not store above 25°C.
If accidentally frozen, shake vigorously before use.

5.4 Nature and composition of immediate packaging

500 ml and 1lfluorinated high-density polyethylene containers with PP screw cap closure and a polyethylene seal.
2,5l fluorinated high-density polyethylene backpack containers with PP screw cap closure and two PP spouted caps with a nitrile joint.
5l fluorinated high-density polyethylene backpack containers with PP screw cap closure and a PP spouted cap with a nitrile joint.

Pack sizes:
Container of 500 ml
Container of 1 l
Container of 2,5 l
Container of 5 l

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)

VPA10387/012/001

8. DATE OF FIRST AUTHORISATION

09/12/2013

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

12/10/2026

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).