SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Cydectin LA 20 mg/ml Solution for Injection for Sheep

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance:

Moxidectin 20 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)	70.0 mg
Sorbitan Oleate	
Propylene glycol dicaprylocaprate	
Butylhydroxytoluene	≤ 0.12 mg

Clear yellow solution for injection.

3. CLINICAL INFORMATION

3.1 Target species

Sheep (above 15 kg bodyweight).

3.2 Indications for use for each target species

Treatment and prevention of mixed infections of gastro-intestinal nematodes, respiratory nematodes and certain arthropod parasites in sheep.
Moxidectin is indicated for treatment of infections caused by moxidectin sensitive strains of:

– **Gastro-intestinal nematodes:**
. *Haemonchus contortus* (adults and L3)
. *Ostertagia (Teladorsagia) circumcincta* (adults and L3, including inhibited larvae)
. *Trichostrongylus axei* (adults)
. *Trichostrongylus colubriformis* (adults and L3)
. *Nematodirus spathiger* (adults)
. *Cooperia curticei (macmasteri)* (adults)
. *Cooperia punctata* (adults)

. *Oesophagostomum columbianum* (L3)
. *Chabertia ovina* (adults)

– **Respiratory tract nematodes:**
Dictyocaulus filaria (adults)

– **Larvae of Diptera:**
. *Oestrus ovis*: L1, L2, L3
– **Mange mites:**
. *Psoroptes ovis*

The product has a persistent action and protects sheep against infection or re-infection with the following parasites for the period indicated:

Species	**Protection period (days)**
Ostertagia (Teladorsagia) circumcincta	97
Haemonchus contortus	111
Trichostrongylus colubriformis	44
Psoroptes ovis	60

Persistent efficacy periods have not been established for parasite species other than those included in the list above. Therefore, re-infection of animals on pasture contaminated by parasites other than these remains possible before the 44-day minimum persistency period demonstrated for specific species.

3.3 Contraindications

Do not use in sheep less than 15 kg bodyweight.
Do not inject the product by intravascular route. Intravascular injection may result in ataxia, paralysis, convulsions, collapse and death. See item “Special precautions for safe use in the target species”
Do not use in cases of hypersensitivity to the active substance or to any excipients.

3.4 Special warnings

Unnecessary use of antiparasitics or use deviating from the instructions given in the SPC may increase the resistance selection pressure and lead to reduced efficacy. The decision to use the product should be based on confirmation of the parasitic species and burden, or of the risk of infestation based on its epidemiological features, for each individual herd.

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
- Underdosing, which may be 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.

Resistance to macrocyclic lactones has been reported in *Teladorsagia* in sheep in a number of countries. In 2008, throughout Europe, moxidectin resistance is very rare; it has been reported in a single case involving a levamisole-, benzimidazole and ivermectin-resistant strain of *Teladorsagia circumcincta*. Therefore, the use of moxidectin should be based on local (regional, farm) epidemiological information about susceptibility of nematodes, local history of treatments and recommendations on how to use the product under sustainable conditions to limit further selection for resistance to anthelmintics. These precautions are especially important when moxidectin is being used to control resistant strains.

Trials have shown that moxidectin is effective against certain strains of *Haemonchus contortus*, *Teladorsagia circumcincta* and *Trichostrongylus* spp. resistant to benzimidazoles.
Psoroptes ovis is an extremely contagious external parasite of sheep and cattle. To ensure complete control, great care must be taken to avoid re-infestation, as mites may be viable for up to 15 days off the animal. It is important that all animals which have been in contact with infected ones are treated with an appropriate product. Contact between treated, infected and untreated herds must be avoided until at least seven days after treatment.

Resistance to moxidectin has been reported in *Psoroptes ovis* scab mites in sheep and in cattle. Cases of side-resistance with other macrocyclic lactones (ivermectin and doramectin) have been reported as well. The use of this product should take into account local information about susceptibility of the target parasites, where available.

3.5 Special precautions for use

Special precautions for safe use in the target species:

This product has been formulated specifically for subcutaneous injection in the base of the ear of sheep and must not be given by any other route of administration or to any other species.

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. If this occurs, it is unlikely that any product related symptoms will be observed. In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.
Advice to Medical Practitioners in case of accidental self-injection: treat symptomatically.

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 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.

3.6 Adverse events

Sheep:

Very common (>1 animal / 10 animals treated):	Injection site swelling[1] Injection site inflammation
Rare (1 to 10 animals / 10,000 animals treated):	Increased salivation [2] Ataxia[2], Drowsiness[2] Depression[2]
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Neurological disorder[3] (such as collapse, convulsion, paralysis)

[1] generally resolves without any treatment within 7 days
[2] transitory, no specific antidote, no particular treatment is required: these symptoms usually disappear within 24 to 48 hours
[3] Severe reactions may be fatal.

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 its local representative or the national competent authority via the national reporting system. See also the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy:
Can be used during pregnancy. However, note 3.3. Contraindications.

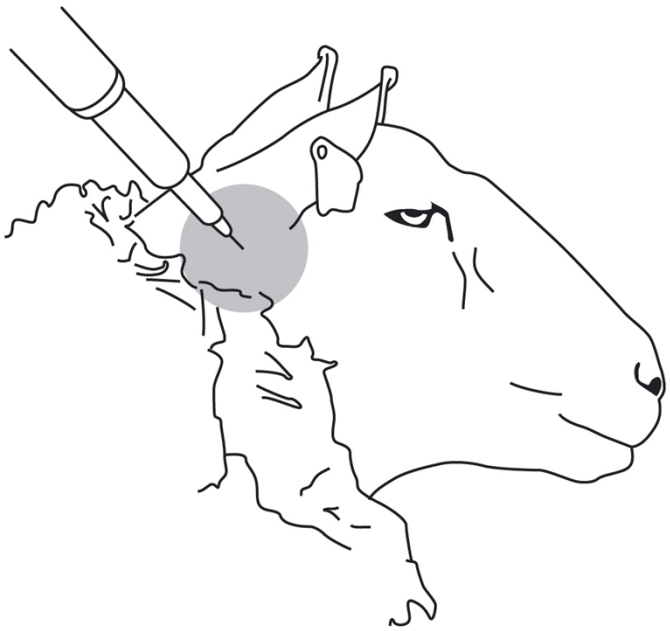
3.8 Interaction with other medicinal products and other forms of interaction

The effects of GABA agonists are increased by moxidectin.

3.9 Administration routes and dosage

Subcutaneous use.
Dosage is 0.5 ml/10 kg bodyweight to give 1 mg moxidectin/ kg bodyweight. The 50 ml vial stoppers must not be broached more than 10 times. Use automatic syringe equipment for the 200 ml and 500 ml vials.
Underdosing could result in ineffective use and may favour resistance development. To ensure administration of a correct dose, bodyweight 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 bodyweight and dosed accordingly, in order to avoid under- or overdosing.
The injection should be administered as a single subcutaneous injection at the base of the ear using an 18 gauge, 25 mm hypodermic needle. With the animal's head under control, the formulation should be administered about 2 cm caudal from the anterior (rostral) edge of the pinna at the base of the ear. The skin at the base of the selected ear should be pinched and the product injected into the subcutaneous tissue. Following subcutaneous administration, the needle should be withdrawn from the skin as pressure is applied with the thumb at the point of insertion for several seconds. If leakage occurs then pressure should be applied for several additional seconds.

Diagram: Ear injection procedure



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

Signs of overdoses have not been seen at 3 and 5 times the recommended dose. However, if they do occur they should be consistent with the mode of action of moxidectin and would be manifested as transient salivation, depression, drowsiness and ataxia 24 to 36 hours post-treatment. The signs would usually disappear within 36 to 72 hours without treatment. 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

To be completed in accordance with national requirements after conclusion of the MRP.

3.12 Withdrawal periods

Meat and offal: 104 days.

Milk: Not permitted for use in dairy sheep, at any stage of life.

The withdrawal period is based solely on a single injection at the base of the ear.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QP54AB02

4.2 Pharmacodynamics

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 interacts with GABA receptors and chloride channels. 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.
The product has a persistent activity against the second instar larvae of *Oestrus Ovis* (L2 Larvae only) up to 80 days after treatment.
However, re-infestation with 1st instar larvae is not prevented and clinical signs arising from such re-infestation may be observed during this period.
Resistance to moxidectin is mediated in part by membrane transporter P-glycoproteins, and cross resistance with other macrocyclic lactones is possible.

4.3 Pharmacokinetics

Moxidectin is absorbed following subcutaneous injection with maximum blood concentrations (C_{max} 24 ng/ml) being achieved 4 to 7 days post injection. Mean AUC_{last} is 411 ng.d/ml. The drug is distributed throughout the body tissues but due to its lipophilicity it is concentrated mainly in the fat. The depletion half life in fat is 30 - 34 days.

Moxidectin undergoes biotransformation by hydroxylation in the body. 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: 3 years.
Shelf life after first opening the immediate packaging: 28 days.

5.3 Special precautions for storage

Do not store above 25°C. Keep the container in the outer carton in order to protect from light.

5.4 Nature and composition of immediate packaging

Natural high density polyethylene vials with Flurotec coated chlorinated butyl rubber stoppers and aluminium flip off seals (50 ml) or aluminium seals (200 ml, 500ml). Each vial is supplied in a carton.

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

Vm 60021/3057

8. DATE OF FIRST AUTHORISATION

13 January 2009

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

February 2025

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).

Gavin Hall

Approved: 26 February 2025