SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Cydectin 1% w/v solution for injection for sheep

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance:
Moxidectin 10.0 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	40.0 mg
Butylated hydroxytoluene (E321)	2.5 mg
Polysorbate 80	
Propylene glycol	
Disodium edetate dehydrate	
Sodium phosphate anhydrous	
Sodium acid phosphate monohydrate	
Water for injections	

A sterile, clear to pale yellow aqueous solution.

3. CLINICAL INFORMATION

3.1 Target species

Sheep.

3.2 Indications for use for each target species

The veterinary medicinal product is indicated for:

Prevention and treatment of Psoroptic mange (*Psoroptes ovis*):

Clinical cure: 2 injections 10 days apart.
Preventive efficacy: 1 injection.

Treatment and control of infestations caused by moxidectin sensitive strains of:

Gastro-intestinal nematodes:
- *Haemonchus contortus*
- *Teladorsagia circumcincta* (including inhibited larvae)
- *Trichostrongylus axei* (adults)
- *Trichostrongylus colubriformis* (adults and L3)
- *Nematodirus spathiger* (adults)
- *Cooperia curticei* (adults)
- *Cooperia punctata* (adults)
- *Gaigeria pachyscelis* (L3)
- *Oesophagostomum columbianum* (L3)
- *Chabertia ovina* (adults)

Respiratory tract nematode:
- *Dictyocaulus filaria* (adults)

Larvae of Diptera
- Oestrus ovis: L1, L2, L3

The veterinary medicinal product has a persistent effect in preventing infestation or reinfestation for:
- At least 4 weeks against *Psoroptes ovis*
- 5 weeks against *Teladorsagia circumcincta* and *Haemonchus contortus*
- 4 weeks against *Gaigeria pachyscelis* and *Oesophagostomum columbianum*
- 2 weeks against *Trichostrongylus colubriformis*

Trials have shown that the product may be effective against strains of *Haemonchus contortus* resistant to benzimidazoles, ivermectin and doramectin.

3.3 Contraindications

Do not use in animals vaccinated against footrot.

3.4 Special warnings

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 bodyweight, 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.

A single injection will protect against scab for at least 28 days but contact with infected sheep after this time may result in infestation. All bought-in or returning animals should be treated and isolated for at least 12 days.

3.5 Special precautions for use

Special precautions for safe use in the target species:
It is important to treat at the recommended dosage and to avoid under-dosing since this will result in spread of sheep scab.

Signs of sheep scab can be confused with chewing louse infestation, against which the product is not effective.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.
In case of contact with skin and eyes wash affected area with clean water.
Do not smoke, eat or drink while handling the product.
Wash hands after use.

To the physician: In cases of accidental self-injection treat any specific signs 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

None known.

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:
Can be used during pregnancy.

3.8 Interaction with other medicinal products and other forms of interaction

No known incompatibility with concurrent administration of mineral supplements or fluke treatments.

3.9 Administration routes and dosage

Subcutaneous use.

0.1 ml/5 kg live bodyweight, equivalent to 0.2 mg moxidectin/kg live bodyweight given subcutaneously in the neck using a needle of 18-gauge (1.2 mm) diameter or less and 1/2 inch (1.5 cm) length.

When treating groups of animals, use only the CYDECTIN Automatic Injector and vented draw-off system. For the treatment of individual sheep, a syringe not exceeding 2.5 ml and calibrated in increments of 0.1 ml should be used.

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.

Syringes must be filled from the vial through a dry, sterile draw-off needle that has been placed in the vial stopper. Vial stoppers must not be broached more than 10 times.

For routine prevention of sheep scab, all sheep in the flock must be injected once.

The curative treatment of scab requires two injections 10 days apart.
The two injections must be given on different sides of the neck.

The first dose should be given at around 4-6 weeks of age to lambs to control worms, with a second dose 6 weeks later, if necessary.

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

The symptoms of overdose are consistent with mode of action of moxidectin and generally do not occur at less than 10 times the recommended dose. They are manifested as transient salivation, depression, drowsiness, and ataxia 8 and 12 hours post-treatment. No treatment is generally necessary. The symptoms resolve in 24 to 48 hours. 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: 70 days.
Milk: Not authorised for use in animals producing milk for human consumption.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QP54AB02

Endectocides: macrocyclic lactones

4.2 Pharmacodynamics

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 interference with neuromuscular transmission of the GABA (gamma amino butyric acid) -gated or glutamate-gated chloride channels.

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. These results in flaccid paralysis and eventual death of parasites exposed to the drug.

4.3 Pharmacokinetics

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 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.

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.

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: 6 months.

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

High density polyethylene containers of 50, 200, and 500 ml content sealed with bromobutylated rubber bung and aluminium alloy inner seal.

Not all pack sizes may be marketed.

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

Medicines should not be disposed of via wastewater.

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 material 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 UK Limited

7. MARKETING AUTHORISATION NUMBER

Vm 42058/5158

8. DATE OF FIRST AUTHORISATION

17 July 1998

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

October 2025

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCT

Veterinary medicinal product subject to prescription.

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

Gavin Hall

Approved: 14 January 2026