

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

Active substance:

	% w/v
Moxidectin	1.000

Excipient(s):

Benzyl Alcohol	4.000
Butylhydroxytoluene (E321)	0.250

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Solution for injection.
A sterile, clear to pale yellow aqueous solution.

4. CLINICAL PARTICULARS

4.1 Target species

Sheep

4.2 Indications for use, specifying the target species

CYDECTIN 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 infections caused by moxidectin sensitive strains of:

Gastro-intestinal nematodes:

- *Haemonchus contortus*
- *Ostertagia (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

CYDECTIN has a persistent effect in preventing infection or reinfection for:

- At least 4 weeks against *Psoroptes ovis*
- 5 weeks against *Ostertagia circumcincta* and *Haemonchus contortus*
- 4 weeks against *Gaigeria pachyscelis* and *Oesophagostomum columbianum*
- 2 weeks against *Trichostrongylus colubriformis*

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

4.3 Contraindications

Not to be used in animals vaccinated against footrot.

4.4 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.

4.5 Special precautions for use

(i). Special precautions for use in animals

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.

(ii). Special precautions to be taken by the person administering the veterinary medicinal product to animals

Care should be taken to avoid self-injection.

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.

Advice to medical practitioners: In cases of accidental self-injection treat any specific signs symptomatically.

4.6 Adverse reactions (frequency and seriousness)

None known.

4.7 Use during pregnancy, lactation or lay

Extensive studies in laboratory animals and cattle have shown no adverse effects during pregnancy.

4.8 Interaction with other medicinal products and other forms of interaction

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

4.9 Amounts to be administered and administration route

0.1ml/5 kg live bodyweight, equivalent to 0.2mg moxidectin/kg live bodyweight given subcutaneously in the neck using a needle of 18 gauge (1.2mm) 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 over dosing.

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.

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

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.

4.11 Withdrawal period

Meat and offal: 70 days.

Milk: Not for use in sheep producing milk for human consumption or Industrial purposes, including the dry period.

5. PHARMACOLOGICAL PROPERTIES

ATCvet Code: QP54AB02

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.

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.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Benzyl Alcohol
Polysorbate 80
Propylene glycol
Butylated hydroxytoluene (E321)
Disodium edetate dehydrate
Sodium phosphate anhydrous
Sodium acid phosphate monohydrate
Water for injections

6.2 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: 3 years.
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.
Following withdrawal of the first dose, use the product within 6 months.

6.5 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.

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 materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

DANGEROUS to fish and aquatic life. Do not contaminate ponds, waterways and ditches with the product or used containers.

7. MARKETING AUTHORISATION HOLDER

Zoetis UK Limited
5th Floor, 6 St. Andrew Street
London
EC4A 3AE

8. MARKETING AUTHORISATION NUMBER

Vm 42058/4027

9. DATE OF FIRST AUTHORISATION

Date: 17 July 1998

10. DATE OF REVISION OF THE TEXT

Date: October 2013



Approved: 07/10/2013