

CYDECTIN 0.1% Oral Solution for Sheep

PRESENTATION

A pale yellow solution containing 1 mg/ml moxidectin. Also contains the excipients benzyl alcohol, butylhydroxytoluene and disodium edentate.

USES

Moxidectin is a second generation macrocyclic lactone of the milbemycin family.

CYDECTIN 0.1% Oral Drench for Sheep is indicated for the treatment and prevention of infections caused by:

Mature (adult) and immature (L4) gastro-intestinal nematodes

- *Haemonchus contortus* (including inhibited larvae)
- *Ostertagia circumcincta* (including inhibited larvae)
- *Ostertagia trifurcata*
- *Trichostrongylus axei* (including inhibited larvae)
- *Trichostrongylus colubriformis*
- *Trichostrongylus vitrinus*
- *Nematodirus battus*
- *Nematodirus spathiger*
- *Nematodirus filicollis* (adults only)
- *Strongyloides papillosus* (larval stages only)
- *Cooperia curticei* (adults only)
- *Cooperia oncophora*
- *Oesophagostomum columbianum*
- *Oesophagostomum venulosum* (adults only)
- *Chabertia ovina*
- *Trichuris ovis* (adults only)

Adult respiratory tract nematode

- *Dictyocaulus filaria*

CYDECTIN 0.1% Oral Drench for Sheep has a persistent effect in preventing reinfection by *Ostertagia circumcincta* and *Haemonchus contortus* for 5 weeks and *Oesophagostomum columbianum* for 4 weeks.

Clinical trials have shown that CYDECTIN 0.1% Oral Drench for Sheep is effective against certain benzimidazole resistant strains of *Haemonchus contortus*, *Ostertagia circumcincta*, *Trichostrongylus colubriformis* and *Cooperia curticei*.

DOSAGE AND ADMINISTRATION

CYDECTIN should be given as a single oral drench of 1 ml/5 kg live bodyweight, equivalent to 200 µg moxidectin/kg live bodyweight using the CYDECTIN drench gun or any standard drenching equipment.

To ensure a correct dosage, bodyweight should be determined as accurately as possible; accuracy of the dosing 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. Do not mix with other products.

CONTRA-INDICATIONS, WARNINGS, ETC

The effects of GABA agonists are increased by moxidectin.

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 this product should be based on local (regional, farm) epidemiological information about susceptibility of parasites, local history of treatments and recommendations on how to use the product under sustainable conditions to limit further selection for resistance to antiparasitic compounds. These precautions are especially important when moxidectin is being used to control resistant strains.

Withdrawal Period

Meat and offal: 14 days

Milk: 120 hours

Operator warnings

Avoid direct contact with skin and eyes.

Do not smoke, drink or eat when using the product.

Wear impermeable rubber gloves during use.

Wash hands after use.

PHARMACEUTICAL PRECAUTIONS

Protect from light. Do not store above 25°C.

When the container is breached (opened) for the first time, using the in-use shelf-life which is specified on this package insert, the date on which any product remaining in the container should be discarded should be worked out. This discard date should be written in the space provided on the label and carton.

Dangerous to fish and aquatic life. Do not contaminate ponds, waterways or ditches with product or used containers. Any unused veterinary medicinal product or waste material derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

Shelf-life after first opening the immediate packaging: 6 months.

Keep out of the reach and sight of children.

For animal treatment only.

LEGAL CATEGORY

POM-VPS

PACKAGING QUANTITIES

HDPE 1 litre jerrycan and 2.5 and 5.0 litre LDPE flexipacks. Not all pack sizes may be marketed.

FURTHER INFORMATION

Moxidectin is a member of the 3-ML anthelmintic class.

Moxidectin has been shown to be safe for use in pregnant, lactating and breeding animals.

CYDECTIN 0.1% Oral Drench for Sheep has a wide margin of safety and symptoms of overdose do not generally occur at less than 5 times the recommended dose. They are manifested as transient salivation, depression, drowsiness and ataxia 8 to 12 hours post-treatment. Treatment is not generally necessary and recovery is generally complete within 24 to 48 hours. There is no specific antidote.

Dosing Guidelines

CYDECTIN 0.1% Oral Drench for Sheep gives optimal pasture protection against stomach worms *Ostertagia* sp and *Haemonchus* sp, with an 8 week dosing interval–i.e. 5 week persistent activity, plus a 3 week interval from any re-infection to the presence of eggs in the dung.

Ewes

Treat at or around lambing to minimise the "spring rise", and pre-tupping, when rams should be treated also.

After treatment, CYDECTIN 0.1% Oral Drench for Sheep continues to kill stomach worms picked up by the ewe for 5 weeks, thus substantially reducing pasture contamination. This "vacuum-cleaning" effect greatly reduces the worm challenge to lambs grazing the same pasture.

Lambs

The first dose should be given at around 4-6 weeks of age, with a second dose, if required 8 weeks later. Additional treatment may be required where there is a *Nematodirus* challenge.

Nematodirus

Treat lambs when a challenge is expected. CYDECTIN 0.1% Oral Drench for Sheep effectively controls *Nematodirus* at the time of dosing, but as with other available wormers does not offer a persistent effect against *Nematodirus*.

MARKETING AUTHORISATION NUMBER

Vm 42058/4024.