

CYDECTIN 20 mg/ml LA Solution for Injection for Sheep

PRESENTATION

A clear yellow liquid containing moxidectin 20 mg/ml as the active substance.

Excipients: Benzyl alcohol 70 mg/ml.

USES

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*

Trials have shown that moxidectin is effective against certain strains of *Haemonchus contortus*, *Ostertagia (Teladorsagia) circumcincta* and *Trichostrongylus* spp. resistant to benzimidazoles. The product has a persistent action and protects sheep against infection or re-infection with the following parasites for the period indicated:

Species	Days
<i>Ostertagia (Teladorsagia) circumcincta</i>	97
<i>Haemonchus contortus</i>	111
<i>Trichostrongylus colubriformis</i>	44
<i>Psoroptes ovis</i>	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.

DOSAGE AND ADMINISTRATION

Dosage is 0.5 ml/10kg 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.

Use the following table as a guide:

	No of doses per pack			
Weight of sheep kg	Dose ml	50 ml	200 ml	500 ml

20	1.0	50	200	500
30	1.5	33	133	333
40	2.0	25	100	250
50	2.5	20	80	200
60	3.0	17	67	167
70	3.5	14	57	143
80	4.0	13	50	125
90	4.5	11	44	111
100	5.0	10	40	100

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.

CONTRA-INDICATIONS, WARNINGS, ETC

Do not use in sheep less than 15 kg bodyweight.

Do not use in cases of hypersensitivity to the active substance or to any excipients.

Swelling and inflammation may be found at the injection site in some animals following treatment. The swelling generally disappears within 7 days of treatment and generally resolves without any medical treatment required. In rare cases, adverse reactions such as transitory salivation, depression, drowsiness and ataxia might occur. No particular treatment is required; these symptoms usually disappear within 24 to 48 hours. There is no specific antidote.

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.

CYDECTIN 20 mg/ml LA for Sheep 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.

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.

Withdrawal period:

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.

Operator warnings:

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. Advice to Medical Practitioners in case of accidental self injection: Treat symptomatically.

PHARMACEUTICAL PRECAUTIONS

Do not store above 25°C.

Keep the container in the outer carton to protect from light.

Do not use after the expiry date stated on the carton after "EXP".

Shelf-life after first opening the container: 28 days.

When the container is broached (opened) for the first time, using the in-use shelf life which is specified on this package leaflet, 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.

Extremely dangerous for fish and aquatic organisms. Do not contaminate ponds, waterways or ditches with the product or empty container. Any unused product or waste material should be disposed of in accordance with local requirements.

Keep out of the sight and reach of children.

For animal treatment only.

LEGAL CATEGORY

POM-VPS

PACKAGING QUANTITIES

The product is packaged in 50 ml, 200 ml and 500 ml HDPE containers. Not all pack sizes may be marketed.

FURTHER INFORMATION

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

MARKETING AUTHORISATION NUMBER

Vm 42058/4029