

CYDECTIN TriclaMox 1 mg/ml + 50 mg/ml Oral Solution for Sheep

PRESENTATION

Oral Solution.

A clear yellow to brown liquid.

Each ml contains:

Active substance:

Moxidectin 1 mg

Triclabendazole 50 mg

Excipients:

Benzyl alcohol 40 mg

Butylhydroxytoluene 1 mg

USES

For the treatment of mixed nematode and fluke infections in sheep, caused by moxidectin and triclabendazole sensitive strains of:

| Parasite | Treatment | | |
|---------------------------------------|-------------|----|------------------|
| | Adult Stage | L4 | Inhibited stages |
| Gastro-intestinal nematodes: | | | |
| <i>Haemonchus contortus</i> | X | X | X |
| <i>Teladorsagia circumcincta</i> | X | X | X |
| <i>Ostertagia trifurcata</i> | X | X | |
| <i>Trichostrongylus axei</i> | X | X | X |
| <i>Trichostrongylus colubriformis</i> | X | X | |
| <i>Trichostrongylus vitrinus</i> | X | X | |
| <i>Nematodirus battus</i> | X | X | |
| <i>Nematodirus spathiger</i> | X | X | |
| <i>Nematodirus filicollis</i> | X | | |
| <i>Strongyloides papillosus</i> | | X | |
| <i>Cooperia curticei</i> | X | | |
| <i>Cooperia oncophora</i> | X | X | |
| <i>Oesophagostomum columbianum</i> | X | X | |
| <i>Oesophagostomum venulosum</i> | X | | |
| <i>Chabertia ovina</i> | X | X | |
| <i>Trichuris ovis</i> | X | | |
| Respiratory tract nematode: | | | |
| <i>Dictyocaulus filaria</i> | X | | |

| Liver fluke | Adult Stage | Early Immature | Late Immature |
|--------------------------|-------------|----------------|---------------|
| <i>Fasciola hepatica</i> | X | X | X |

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

| Species | Protection period (days) |
|----------------------------------|--------------------------|
| <i>Teladorsagia circumcincta</i> | 35 |
| <i>Haemonchus contortus</i> | 35 |

Clinical trials, after experimental and natural infection, have shown that the product is effective against certain benzimidazole resistant strains of:

Haemonchus contortus

Teladorsagia circumcincta

Trichostrongylus colubriformis

Cooperia curticei

DOSAGE AND ADMINISTRATION

For oral use:

Should be given as a single oral drench of 1 ml/5 kg bodyweight, equivalent to 0.2 mg moxidectin/kg bodyweight and 10 mg triclabendazole/kg bodyweight, using any standard drenching equipment.

To ensure a correct dosage, 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. All animals in a group should be treated.

CONTRA-INDICATIONS, WARNINGS, ETC

Do not use in cases of hypersensitivity to the active substance(s) or to any of the excipient(s).

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*. Resistance to triclabendazole has been reported in *Fasciola hepatica* in sheep in some European countries. 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.

This product should not be used for the treatment of single infections.

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

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/or triclabendazole and would be manifested as

transient salivation, depression, drowsiness, ataxia and reduced food intake 8 to 12 hours post-treatment. Treatment is not generally necessary and recovery is generally complete within 1 to 5 days. There is no specific antidote.

This product is safe for use in breeding animals.

Withdrawal period:

Meat and offal: 31 days

Milk: not authorised for use in ewes producing milk intended for human consumption including during the dry period. Do not use within 1 year prior to the first lambing in ewes intended to produce milk for human consumption.

Operator warning:

Avoid direct contact with skin and eyes.

Wash hands after use.

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

Wear impermeable rubber gloves during use.

PHARMACEUTICAL PRECAUTIONS

Do not store above 25°C.

Protect from light.

Do not freeze.

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

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

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.

The product should not enter water courses as this may be dangerous for fish and other aquatic organisms. Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

Keep out of the ~~reach-sight~~ and ~~reachsight~~ of children.

For animal treatment only.

LEGAL CATEGORY

POM-VPS

PACKAGING QUANTITIES

The product is packaged in 1L, 2.5L and 5L 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 42058/4030