

## CYDECTIN 1% Injectable Solution for Sheep

### PRESENTATION

A sterile, clear to pale yellow, aqueous solution containing 1.0% w/v moxidectin per litre (active substance); 4.0% w/v benzyl alcohol (solubiliser and antimicrobial preservative); 0.25% w/v butylated hydroxytoluene (antioxidant).

### USES

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

For the prevention and treatment of psoroptic mange (scab) in sheep.

For the treatment and control of infections caused by moxidectin sensitive strains of the following endoparasites and ectoparasites:

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*

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.

### ROUTINE PREVENTION OF SCAB

One injection at the recommended dosage will protect against *Psoroptes ovis* (scab mite) infestation for at least 28 days.

### TREATMENT OF SCAB OUTBREAKS

Two injections at the recommended dosage, 10 days apart.

### DOSAGE AND ADMINISTRATION

#### Dosage

0.1 ml per 5 kg live bodyweight to give 0.2 mg moxidectin/kg live bodyweight.

#### Administration

Inject subcutaneously (under the skin) in the neck. Use sterile 18 gauge needles or smaller, of half inch (1.5 cm) length. Ensure that the needle is inserted carefully under the skin using aseptic precautions and that product does not leak from the injection site. Be certain that the needle has penetrated the skin before delivering the dose. 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.

**DO NOT UNDERDOSE.** As with any scab treatment, underdosing can cause suppression and spread of the disease. When treating groups of animals, use only the CYDECTIN Automatic Injector and vented draw-off system. For treatment of individual sheep, a syringe not exceeding 2.5 ml and calibrated in increments of 0.1 ml should be used.

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 breached 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.

### **CONTRA-INDICATIONS, WARNINGS, ETC**

Not to be used in animals that have any history of previous vaccination against footrot.

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.

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

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

Do not mix with any other veterinary medicinal products before administration.

Read entire package leaflet before using this product.

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 periods*

Meat and offal: 70 days

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

#### *Operator warnings*

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.

### **PHARMACEUTICAL PRECAUTIONS**

Do not store above 25°C.

Protect from light.

Following withdrawal of the first dose, use the product within six months.

When the container is breached for the first time, the date on which any product remaining in the container should be calculated. A statement of in-use shelf life is given on the package insert. This discard date should be written in the space provided on the label.

Keep container in outer carton.

DANGEROUS to fish and aquatic life. Do not contaminate ponds, waterways or ditches with product or used containers. Dispose of any unused product and empty containers in accordance with guidance from your local waste regulation authority.

Keep out of reach and sight of children.

For animal treatment only.

## LEGAL CATEGORY

POM-VPS

## PACKAGING QUANTITIES

50 ml , 200 ml and 500 ml high density polyethylene containers. Not all pack sizes may be marketed.

## FURTHER INFORMATION

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

Clinical trials have shown that there are no signs of pain after injection and no irritation at the injection site.

CYDECTIN 1% Solution for Injection for Sheep has a wide margin of safety and symptoms of overdosage do not generally occur at less than 10 times the recommended dose. They are manifested as transient salivation, depression, drowsiness and ataxia 8 to 12 hours post-treatment. No treatment is generally necessary. The symptoms resolve in 24 to 48 hours. There is no specific antidote.

There are no known interactions with other animal health products used routinely in sheep such as mineral supplements, fluke or worm treatments, or clostridial vaccines.

## PREVENTION AND TREATMENT OF SCAB

### *Prevention of scab*

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

A single injection with CYDECTIN will protect against sheep scab for at least 28 days from the time of treatment. If sheep come in contact with infected animals after that time, infestation can occur.

All bought-in or returned animals should be treated and isolated for 12 days before mixing with the rest of the flock.

Ensure adequate fencing between neighbouring flocks.

It has been demonstrated that a single injection of all sheep in an area (with a double treatment of any clinically affected animals) is an effective alternative to routine autumn dipping to eradicate sheep scab.

### *Treatment of Scab Outbreaks*

Inject all sheep in the affected flock or sub-flock, twice, 10 days apart.

The two injections must be given on different sides of the neck.

It is important to ensure that all in-contact sheep are treated.

Sheep scab mites can remain infective off the animal, on fences, posts etc. for at least 16 days. Since CYDECTIN protects for at least 28 days (i.e. longer than the time for which scab mites can remain infective off the animal), treated sheep can be immediately turned back onto the same pasture after dosing.

Since the effect of any injectable on scab mites is not immediate, contact between treated infected sheep and non-treated, non-infected sub-flocks must be avoided until at least 12 days after the last treatment.

## TREATMENT AND CONTROL OF WORMS

### *Dosing guidelines*

CYDECTIN is a member of the avermectin/milbemycin 3-ML class of anthelmintics. The advice of a veterinary surgeon should be sought in using CYDECTIN 1% Solution for Injection for Sheep in a dosing programme, to ensure correct diagnosis of the nematode infection present and to minimise the risk of developing resistance.

CYDECTIN gives optimal pasture protection against stomach worms (*Ostertagia* and *Haemonchus*) with an 8 week dosing interval - i.e. 5 week protection against stomach worm, plus a 3 week interval from any re-infection to the presence of eggs in the dung. More frequent dosing may be required for the treatment and control of intestinal worms (eg *Trichostrongylus* and *Cooperia* spp) due to a less persistent effect against these species of nematode. The following may be used as a guide:

**Ewes:** Treat at or around lambing to minimise the "spring rise", then again pre-tupping, when rams should be treated also.

After treatment, CYDECTIN 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. For treatment and control of winter Trichostrongylosis (Black Scour) dosing may need to be repeated at more frequent intervals due to a less persistent effect against intestinal nematodes.

**Nematodirus:** For treatment and control of *Nematodirus battus*, use CYDECTIN 0.1% Oral Drench for sheep. Read package leaflet carefully before use.

**MARKETING AUTHORISATION NUMBER**  
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