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Animec 0.8mg/ml Oral Solution for Sheep

Species: Sheep

Therapeutic indication: **Pharmaceuticals: Ectoparasiticides:** For sheep, **Pharmaceuticals: Endoparasiticides:** Anthelmintics for sheep

Active ingredient: Ivermectin

Product: Animec Oral for Sheep

Product index: Animec Oral for Sheep

Sheep - meat: 10 days

Withdrawal notes: Do not use in lactating sheep producing milk for human consumption. Sheep must not be treated within 60 days prior to the commencement of lactation, if milk is to be used for human consumption.

Incorporating:

Presentation

Animec Oral is a transparent, yellow coloured solution containing 0.8mg/ml of ivermectin. Each ml also contains Benzyl Alcohol 28.6mg, Butylhydroxyanisole 0.10 mg, Propyl Gallate 0.10 mg

Uses

For the treatment of infections with the following parasites:

Nematodes

Gastrointestinal roundworms (adult and fourth larval stage): *Haemonchus contortus*, *Teladorsagia circumcincta*, *Trichostrongylus* spp., *Cooperia* spp., *Nematodirus* spp. including *N. battus*, *Strongyloides papillosus*, *Chabertia ovina*

Lungworms(adult and fourth larval stage): *Dictyocaulus filaria*

Arthropods

Nasal bot (all larval stages): *Oestrus ovis*

Dosage and administration

The veterinary medicinal product should be given orally. The recommended dose rate is 0.2 mg ivermectin per kg bodyweight (corresponding to 2.5 ml per 10 kg bodyweight).

Over 60 kg give 2.5 ml per 10 kg bodyweight

To ensure administration of a correct dose, body weight 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.

Contra-indications, warnings, etc

- Do not use in animals with known hypersensitivity to the active ingredient or any of the excipients.

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 body weight or misadministration of the product.

Resistance to ivermectin (an avermectin) has been reported in Teladorsagia in sheep and goats within the EU and it is common in Haemonchus in sheep outside the EU. Therefore the use of this product should be based on local (regional, farm) epidemiological information about susceptibility of nematode and recommendations on how to limit further selection for resistance to anthelmintics.

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.

There is cross-resistance with other avermectins and with milbemycins.

Special precautions for use in animals

The timing of treatment should be based on epidemiological factors and should be customised for each individual farm. A dosing programme should be established by the veterinary surgeon.

Veterinary advice should be sought on appropriate dosing programmes and stock management to achieve adequate parasite control, and to reduce the likelihood of anthelmintic resistance developing. Veterinary advice should also be sought if the product does not achieve the desired clinical effect, as other diseases, nutritional disturbances or anthelmintic resistance might be involved.

Avermectins may not be well tolerated in non-target species. Cases of intolerance resulting in fatalities have been reported in dogs, especially Collies, Old English Sheep Dogs and related breeds or crosses, and also in turtles/tortoises.

Special precautions to be taken by the person administering the veterinary medicinal product to animals

Wash hands after use. Avoid contact with skin and eyes.

Do not eat, drink or smoke while handling the product.

Wear impervious gloves when handling or administering the product.

As absorption through skin can occur, in the event of accidental skin contact, wash the affected area immediately with soap and water.

If accidental eye exposure occurs, flush the eyes immediately with water.

Other precautions

None known.

Adverse reactions (frequency and seriousness)

Some sheep may cough immediately after treatment. This passing response is of no consequence.

Use during pregnancy, lactation or lay

The veterinary medicinal product can be administered to ewes at any stage of pregnancy or lactation.

Interaction with other medicinal products and other forms of interaction

None known.

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

At doses up to 4 mg ivermectin per kg administered by stomach tube (20x the recommended dose level) undesirable toxic reactions occurred. Acute symptoms (ataxia, staggering gait, incoordination, depression) were observed at the dose rate of 8 mg/kg (40x the recommended dose level) during a study carried out on 4 animals. Twenty-four hours later, the animals showed only mild incoordination and depression.

Three days post dose all the animals were nearly normal. It is possible that the signs of toxaemia were due to the propylene glycol.

No antidote has been identified. Symptomatic treatment may be beneficial.

Withdrawal periods

Meat and offal: 10 days.

Milk: Do not use in lactating sheep producing milk for human consumption.

Sheep must not be treated within 60 days prior to the commencement of lactation, if milk is to be used for human consumption.

Pharmaceutical precautions

- Do not store above 30°C.
- Shelf life after first opening the container: 18 months.
- EXTREMELY DANGEROUS TO FISH AND AQUATIC LIFE. Do not contaminate surface waters or ditches with product or used container. Any unused product or waste material should be disposed of in accordance with national requirements.

Legal category

Legal category: POM-VPS

Packaging quantities

Flexi pack: 1, 2.5 , 5L and 6L (5L+1L)

Jerri-cans: 1, 2.5, 5L and 10 Litre

Not all pack sizes may be marketed.

Marketing Authorisation Number

VM 08749/4027

Significant changes