Norbrook® Pharmaceuticals Worldwide

DATA SHEET

CLOSAMECTIN POUR ON SOLUTION FOR CATTLE

Region: United Kingdom

PRESENTATION:

Closamectin Pour On treats mixed trematode (liver fluke) and nematode or arthropod infestations due to roundworms, lungworms, eyeworms, warbles, mites and lice of cattle.
Closamectin Pour On is a clear, blue/green, ready-to-use solution containing:
5mg/ml Ivermectin
200mg/ml Closantel.

USES:

For the treatment of mixed trematode (fluke) and nematode or arthropod infestations due to gastrointestinal roundworms, lungworms, eyeworms, warbles, mites and lice of cattle.
Gastrointestinal roundworms (adults and 4th stage larvae):
Ostertagia ostertagi (including inhibited *O. ostertagi*), *Haemonchus placei*, *Trichostrongylus axei*, *Trichostrongylus colubriformis*, Cooperia spp., *Oesophagostomum radiatum*, *Nematodirus helvetianus* (adult), *Strongyloides papillosus* (adult).
Lungworms (adult and 4th stage larvae):
Dictyocaulus viviparus
Trematodes (adult and late immatures):
Fasciola gigantica, *Fasciola hepatica*
Treatment of fluke at 12 weeks (mature) >95% efficacy.
Treatment of fluke at 7 weeks (late immature) >95% efficacy.
Eyeworms (adult):
Thelazia spp.
Cattle grubs (parasitic stages):
Hypoderma bovis, *Hypoderma lineatum*
Lice:
Linognathus vituli, *Haematopinus eurysternus*, *Damalinia bovis*
Mange Mites:
Chorioptes bovis,, *Sarcoptes scabiei* var *bovis*

DOSAGE AND ADMINISTRATION:

Closamectin Pour On should be administered topically at a dosage rate of 500 µg ivermectin per kg bodyweight and 20 mg closantel per kg bodyweight (1ml per 10kg).
The formulation should be applied along the midline of the back in a narrow strip between the withers and the tail head.
Assess bodyweight carefully prior to administration.
The timing for treatment should be based on epidemiological factors and should be customised for each individual farm. A dosing programme should be established by a veterinary professional.
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.

CONTRAINDICATIONS, WARNINGS, Etc:

Animals must not be slaughtered for human consumption during treatment.
Cattle must not be treated within 28 days of slaughter for human consumption.
Do not use in cattle producing milk for human consumption. Do not use in non-lactating dairy cows including pregnant heifers within 60 days of calving.
Closamectin Pour-On can be administered to cattle (including dairy, beef/suckler cattle) at any stage of pregnancy or lactation provided that the milk is not intended for human consumption.
Do not use in cases of known hypersensitivity to the active ingredients.
Do not apply to areas of skin which have mange, scabs or other lesions or to areas contaminated with mud or manure.
Avermectins may not be well tolerated in non-target species (cases of intolerance with fatal outcome are reported in dogs – especially Collies, Old English Sheepdogs and related breeds or crosses, and also in turtles/tortoises).

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 bodyweight, misadministration of the product, or lack of calibration of the dosing device.
The effect of rain on the pour-on formulation at the time of and after application has not been investigated. For maximum effect animals should be kept indoors or undercover following treatment, when there is rain or an imminent risk of rain.
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 tests 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 ivermectin has been reported in *Cooperia* spp in cattle. Therefore the use of this product should be based on local epidemiological information about the susceptibility of the *Cooperia* spp and recommendations on how to limit further selection for resistance to anthelmintics.

***Special Precautions for Use*:**
(i)Special precautions for use in animals:
None. Undesirable effects are not expected when the product is used at the recommended dose rate

(ii)Special precautions to be taken by the person administering the veterinary medicinal product to animals:
The veterinary medicinal product may be irritating to human skin and eyes and the user should be careful not to apply it to himself or other persons. Operators should wear nitrile rubber gloves and boots with a waterproof coat when applying the product. Protective clothing should be washed after use. If accidental skin contact occurs, wash the affected area immediately with soap and water. If accidental eye exposure occurs, flush the eyes immediately with water and get medical attention.
Do not smoke or eat whilst handling the product. Wash hands after use. Use only in well ventilated areas or outdoors.

(iii)Other Precautions Regarding the Environment.
Treated cattle should not have direct access to ponds, streams or ditches for 14 days after treatment.

PHARMACEUTICAL PRECAUTIONS:

EXTREMELY DANGEROUS TO FISH AND AQUATIC LIFE.
Do not contaminate surface water or ditches with the product or used container. Any unused product or waste materials should be disposed of in accordance with national requirements.
Do not store above 25°C**.**
Store upright in original container.
Protect from light.
Discard unused material. Avoid introduction of contamination.
If stored at temperatures below 0°C, Closamectin Pour On Solution for Cattle may appear cloudy. Allowing to warm at room temperature will restore the normal appearance without affecting efficacy.
Flammable – keep away from heat, sparks, open flame or other sources of ignition.

LEGAL CATEGORY:

POM - VPS

PACKAGE QUANTITIES:

Closamectin Pour On is available in 250ml and 1L packs with integral squeeze measure pour system or 1L, 2.5L and 5L for use with a gun delivery system.

FURTHER INFORMATION:

Mode of Action

Ivermectin is an endectocide with activity against a wide range of internal and external parasites. Ivermectin is a macrocylic lactone and acts by inhibiting nerve impulses. It binds selectively and with high affinity to glutamate-gated chloride ion channels which occur in invertebrate nerve and muscle cells. This leads to an increase in the permeability of the cell membrane to chloride ions with hyperpolarization of the nerve or muscle cell, resulting in paralysis and death of the relevant parasites. Compounds of this class may also interact with other ligand-gated chloride channels, such as those gated by the neurotransmitter gamma-aminobutyric acid (GABA). The margin of safety for compounds of this class is attributable to the fact that mammals do not have glutamate-gated chloride channels. The macrocylic lactones have a low affinity for other mammalian ligand-gated chloride channels and they do not readily cross the blood-brain barrier.

Closantel is a member of the salicylanilide class of anthelmintics. Salicylanilides are hydrogen (proton) ionophores (referred to as oxidative phosphorylase uncouplers.) The chemical structure of salicylanilides illustrate the possession of a detachable proton. This type of molecule is lipophilic and is known to shuttle protons across membranes, in particular the inner mitochondrial membrane. Closantel acts by uncoupling oxidative phosphorylation. Closantel is a parasiticide with flukicide activity and efficacy against certain other helminths and arthropods.

At doses of three times the recommended dose, no significant clinical signs were recorded.

Ivermectin

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

Closantel like other salicylanilides is a potent uncoupler of oxidative phosphorylation and the safety index is not as high as is the case of many other anthelmintics. However where used as directed there are unlikely to be any untoward effects. Signs of overdosage can include slight loss of appetite, loose faeces, decreased vision and increased frequency of defecation. High doses may cause blindness, hyperventilation, general weakness and inco-ordination, hyperthermia, convulsions, tachycardia and in extreme cases death. Treatment of overdosage is symptomatic as no antidote has been identified

Pharmacokinetic Properties:
After topical administration of Closamectin Pour-On to cattle at a dose rate of 500 µg ivermectin per kg and 20 mg closantel per kg the following parameters were observed: Ivermectin – Cmax of 19.13 ng/mL and AUC of 2440 ng.hr/mL; Closantel – Cmax of 68.5 µg/mL and AUC of 35207 µg.hr/mL.
IIvermectin is only partially metabolised. In cattle, only about 1 to 2% is excreted in the urine the remainder is excreted in the faeces, approximately 60% of which is excreted as unaltered drug. The remainder is excreted as metabolites or degradation products. Salicylanilides are poorly metabolised and are excreted mainly unchanged. About 90% of closantel is excreted unchanged in the faeces and urine in cattle.

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FOR ANIMAL TREATMENT ONLY

KEEP OUT OF THE REACH AND SIGHT OF CHILDREN