



DATA SHEET

Closamectin Solution for Injection

Region: Republic of Ireland

PRESENTATION

Closamectin Injection is a ready-to-use solution, containing 0.5% w/v ivermectin and 12.5% w/v closantel.

PRODUCT INDICATIONS

For the treatment of mixed trematode (fluke) and nematode or arthropod infestations due to gastrointestinal roundworms, lungworms, eyeworms, warbles, mites and lice of cattle. One dose of Closamectin Injection effectively controls internal and external parasites that impair the health and productivity of cattle.

Gastrointestinal roundworms

Ostertagia ostertagi (including inhibited larval stages), *Ostertagia lyrata* (adult), *Haemonchus placei* (adult and immature), *Trichostrongylus axei* (adult and immature), *Trichostrongylus colubriformis* (adult and immature), *Cooperia oncophora* (adult and immature), *Cooperia punctata* (adult and immature), *Cooperia pectinata* (adult and immature), *Oesophagostomum radiatum* (adult and immature), *Nematodirus helvetianus* (adult), *Nematodirus spathiger* (adult), *Strongyloides papillosus* (adult), *Bunostomum phlebotomum* (adult and immature), *Toxocara vitulorum* (adult), *Trichuris* spp.

Lungworms

Dictyocaulus viviparus (adult and 4th stage larvae)

Liver Fluke (trematodes)

Fasciola gigantica, *Fasciola hepatica*

Treatment of fluke at 12 weeks (mature) >99% efficacy

Treatment of fluke at 9 weeks (late immature) >90% efficacy

Eyeworms (adult)

Thelazia spp.

Cattle grubs (parasitic stages)

Hypoderma bovis, *Hypoderma lineatum*

Lice

Linognathus vituli, *Haematopinus eurytarnus*, *Solenopotes capillatus*

Mange Mites

Psoroptes ovis (syn *P communis* var *bovis*), *Sarcoptes scabiei* var *bovis*

Closamectin Injection may also be used as an aid in the control of the biting louse *Damalinea bovis* and the mange mite *Chorioptes bovis*, but complete elimination may not occur.

Persistent activity in cattle:

Closamectin Injection, at the recommended dose, controls re-infection with:

Prolonged activity

<i>Dictyocaulus viviparus</i>	Up to 21 days
<i>Ostertagia ostertagi</i>	Up to 21 days
<i>Oesophagostomum radiatum</i>	Up to 21 days
<i>Cooperia</i> spp	Up to 14 days
<i>Trichostrongylus axei</i>	Up to 14 days
<i>Haemonchus placei</i>	Up to 14 days

DOSAGE AND ADMINISTRATION

Bodyweight and dosage should be accurately determined prior to treatment to avoid underdosing.

Closamectin Injection should be administered at a dosage rate of 200 mcg ivermectin per kg and 5 mg closantel per kg bodyweight. It should be injected subcutaneously in the middle portion of the neck using the aseptic technique. A maximum dose of 10ml should be administered at any one site with any residual volume administered at another site in the neck. The first dose should be injected into the right neck with any residual volumes injected into separate sites on the left and right neck. A sterile 16-gauge, one-inch needle is recommended. Use of a draw-off needle is recommended to avoid excess broaching of the stopper.

Bodyweight (kg)	Dose Volume (ml)
Up to 50	2
51 - 100	4
101 - 150	6
151 - 200	8
201 - 250	10
251 - 300	12

Over 300 kg bodyweight give 1 ml per 25 kg bodyweight.

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.

MODE OF ACTION

Ivermectin paralyzes and ultimately kills parasitic nematodes, arachnids and insects by its effect on the nervous system of these parasites. At therapeutic doses, ivermectin has no adverse effect on cattle since it does not readily penetrate their central nervous systems. Ivermectin belongs to the avermectin class of anthelmintic endectocides. The mode of action exhibited by the avermectins is unique to this class of antiparasitic agents.

Closantel is a member of the salicylanilide class of anthelmintics. Salicylanilides are hydrogen ionophores which act as potent uncouplers of oxidative phosphorylation. The site of action of these proton ionophores is known to be selective uncoupling of oxidative phosphorylation in parasite mitochondria.

Treatment with Closamectin when flukes are five weeks and greater has been shown to reduce subsequent reproductive capacity and egg shedding.

Low-Volume Injection

Closamectin Injection is highly effective against internal and external parasites at a dose volume of 1 ml per 25 kg bodyweight in cattle. It can be administered quickly and easily.

Avermectins may not be well tolerated in all 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).

Transitory discomfort has been observed in some cattle following subcutaneous administration. Tissue swellings at the injection site are common up to 48 hours after injection which resolve thereafter without treatment. Hardness on palpation may be observed up to 7 days following administration. These reactions resolve without treatment.

Do not use in cases of known hypersensitivity to the active ingredient.

To avoid secondary reactions due to the death of Hypoderma larvae in the oesophagus or in the spine it is recommended to administer the product at the end of warble fly activity and before the larvae reach their resting sites. Consult your veterinarian on the correct timing of treatment.

Overdose: Symptoms of serious closantel overdose are decreased vision or blindness, anorexia, incoordination and general weakness.

CONTRAINDICATIONS, WARNINGS, etc

Animals must not be slaughtered for human consumption during treatment. Cattle must not be slaughtered for human consumption within 49 days of treatment. Not permitted for use in animals producing milk for human consumption, including pregnant animals intended to produce milk for human consumption. Do not use any closantel-containing products during the 49 day withdrawal period. If an additional ivermectin only product is administered within the 49 day withdrawal period set for Closamectin Injection, care should be taken to observe the longest overall withdrawal period.

Do not use in cases of known hypersensitivity to the active ingredients.

This product is not for intravenous or intramuscular use.

Do not smoke, eat or drink while handling the product. Direct contact of the product with the skin should be kept to a minimum. Wash hands after use. Take care to avoid self-injection. Inadvertent self-injection may result in local irritation and/or pain at the injection site.

CONTAINER DISPOSAL

EXTREMELY DANGEROUS TO FISH AND AQUATIC LIFE. Do not contaminate surface waters or ditches with the product or used container. Any unused product or waste materials should be disposed off in accordance with national requirements.

PHARMACEUTICAL PRECAUTIONS

Do not store above 25C.

Protect from light

This product does not contain a preservative.

Use of a draw-off needle is recommended to avoid excess breaching of the stopper.

After first use, discard the vial within 28 days. This date should be recorded on the label. Discard unused material.

Legal category

LM

 Licensed Merchant

PACKAGE QUANTITIES

Closamectin Injection is available in three ready-to-use sizes - 100 ml, 250 ml and 500 ml volumes

NOTE TO USER

Ivermectin belongs to the avermectin [3-AV] class of anthelmintics in the endectocides. Chemical group of anthelmintic endectocides [3-AV]. Closantel is a member of the salicylanilide class of anthelmintics.

Further information for the treatment programmes for mixed infestations consisting of nematodes and/or ectoparasite concurrent with fluke.

The timing for treatment should be based on epidemiological factors and should be customised for each individual farm. As with other anthelmintics, veterinary advice should be sought on appropriate dosing programmes and stock management to achieve adequate parasite control and reduce the likelihood of resistance developing.

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.

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.

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Marketing Authorisation Number:

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For Animal Treatment Only.
Keep out of reach and sight of children.