NOROMECTIN INJECTION VETERINARY

Ivermectin 1.0% w/v 10 mg in 1 ml
For the treatment and control of internal and external parasites of sheep and beef and non-lactating dairy cattle.

Description:
One low-volume dose of Noromectin Injection effectively controls internal and external parasites that impair the health and productivity of cattle and sheep.

Noromectin Injection is a ready-to-use, sterile, non-aqueous solution of ivermectin. Ivermectin is derived from the avermectins, a family of highly active broad spectrum antiparasitic agents which are isolated from fermentation of the soil organism Streptomyces avemitilis.

Noromectin Injection is a 1.0% w/v sterile solution of ivermectin. At the rate of 1 ml per 50 kg bodyweight (0.5 ml per 25 kg) by subcutaneous injections, this formulation will deliver the recommended dosage level of 200 mcg ivermectin per kg bodyweight.

Product Indications:
Noromectin Injection

In Cattle: Noromectin Injection is indicated for the effective treatment and control of the following harmful species of gastrointestinal roundworms, lungworms, eyeworms, warbles, mites and lice of beef and non-lactating dairy cattle.

Psoroptic mange and nasal bots of sheep and gastrointestinal roundworms and lungworms of sheep.

Gastro-Intestinal roundworms: (adult and fourth stage larvae): Ostertagia ostertagi (including inhibited larval stages), Osertagia lyrata, Haemonchus placei, Trichostrongylus axei, Trichostrongylus colubriformis, Cooperia punctata, Cooperia pectinata, Bunostomum phlebotomum, Oesophagostomum radiatum, Strongyloides papillosus (adult), Nematodirus spathiger (adult), and Trichuris spp (adult).
Lungworms: (adult and fourth stage larvae): Dictyocaulus viviparus.
Eyeworms: (adults): Thelazia spp
Warbles: Hypoderma bovis and Hypoderma lineatum
Mange Mltes: Psoroptes bovis, Sarcoptes scabiei var bovis
Sucking Lice: Linognathus vituli, Haemotopinus eurysternus, and Stronyloides capillatus.

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

Noromectin Injection in Sheep
Ivermectin Injection for sheep is indicated for the effective treatment and control of the following harmful species of gastrointestinal roundworms, lungworms, nasal bots and psoroptic mange (sheep scab):
Gastrointestinal roundworms (adults and fourth stage larvae):
Ostertagia circumcincta, O. Trifurcata, Haemonchus contortus, Trichostrongylus axei (adults), Trichostrongylus colubriformis, Trichostrongylus vitrinus (adults), Cooperia curticei, Oesophagostomum venulosum, Oesophagostomum columbianum, Nemotodirus filicollis, Chabertia ovina, Trichuris ovis (adults)

Inhibited larval stages and Benzimidazole resistant strains of Haemonchus controtus and Oestertagia circumcinacta are also controlled.

Lungworms: Dictyocaulus filarial (adults and fourth stage larvae)
Protostrongylus rufescens (adults)
Mange Mites: Psoroptes Ovis
Nasal Bot: Oestrus ovis (all larval stages)

CONTRAINDICATIONS
Treatment of psoroptic mange (sheep scab) with one injection is not recommended, because although a clinical improvement may be seen, elimination of all mites may not occur.
Sheep scab (*Psoroptes ovis*) is an extremely contagious external parasite of sheep. Following treatment of infected sheep, great care must be taken to avoid re-infestation, as mites may be viable for up to 15 days off the sheep. It is important to ensure all sheep which have been in contact between treated infected and non-treated non-infected flocks must be avoided until at least 7 days after the last treatment.

This product is for subcutaneous administration **only** and should not be given via other routes.

Noromectin Multi Injection is a low volume product for cattle and sheep: it should not be used in other species as adverse reactions, such as fatalities in dogs, may occur.

Transitory discomfort has been observed in some cattle following subcutaneous administration. Tissue swellings at the injection site have been observed. These reactions resolve without treatment. Further information is available upon request. Immediately following injection activity suggesting pain, sometimes intense but usually transient has been observed in some sheep.

ADVERSE REACTIONS
If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION
To ensure administration of a correct dose, bodyweight should be determined as accurately as possible; accuracy of the dosing device should be checked.
Noromectin Injection should be given only by subcutaneous injection at the recommended dosage level of 200 mcg ivermectin per kilogram bodyweight in cattle and sheep. Each ml contains 10 mg of ivermectin sufficient to treat 50 kg of bodyweight. For young lambs weighing less than 12.0 kg ensure that the appropriate dose is given (0.1 ml/5 kg bodyweight).

For Cattle- Use the following dosage schedule.

Bodyweight (kg)	Dose Volume (ml)
Up to 50	1.0
51 to 100	2.0
101 to 150	3.0
151 to 200	4.0
201 to 250	5.0
251 to 300	6.0
301 to 350	7.0
351 to 400	8.0
401 to 450	9.0
451 to 500	10.0
501 to 550	11.0
551 to 600	12.0

580

When treating sheep of less than 16 kg seek veterinary advice regarding the use of 1 ml disposable syringes graduated in increments of 0.1 ml.

For the treatment of individual sheep a syringe not exceeding 2.0 ml and calibrated in increments of 0.1 ml should be used.

For Sheep- Use the following dosage schedule:

Bodyweight (kg)	Dose Volume (ml)
Up to 5	0.1
5.1 to 10	0.2
10.1 to 15	0.3
15.1 to 25	0.5
25.1 to 50	1.0
50.1 to 75	1.5
75.1 to 100	2.0

Noromectin Injection is to be given subcutaneously only: Inject under the loose skin in front of or behind the shoulder.
Use of a 17 gauge, half-inch (15-20 mm) needle is suggested. Replace with a fresh sterile needle after every 10-12 animals. Injection of animals with wet or dirty hides is not recommended.

For the treatment and control of Psoroptes ovis (sheep scab) two injections with a seven day interval are required to treat clinical signs of scab and to eliminate living mites.

ADVICE ON CORRECT ADMINISTRATION
Ivermectin paralyses 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 system. Ivermectin belongs to the avermectin class of anthelmintic endectocides.

The suggested dosing programme has been developed to make the best use of the properties of Noromectin Multi Injection. Your veterinary surgeon will be able to provide further advice.

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9/10/15 Proof2: The customer advises that the last sentence should be changed to English to read "The format of this leaflet..."
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Cattle

Stomach and Gut Roundworms
Roundworm larvae may survive on the pasture over the winter in great numbers. They infect grazing cattle immediately after turnout, maturing into egg laying worms and causing increased pasture contamination. Early season treatment with Noromectin Multi Injection keeps down the population of worms in your stock and reduces the number of worm eggs passed onto the pasture to cause later infection.

Ostertagia larvae picked up from the pasture in late summer and early autumn can remain dormant in the stomach wall for many months. In late winter or spring they resume development, resulting in serious disease. Autumn treatment with Noromectin Multi Injection kills these larvae, and prevents Type II ostertagiasis.

Lungworm
Outbreaks of husk (hoose) are most common in summer and autumn. Routine treatment with Noromectin Multi Injection for stomach and gut roundworm control, e.g. at 3 weeks, 8 weeks, and 13 weeks after turnout can be used to control lungworm infection.

Where outbreaks of husk occur, treat promptly with Noromectin Multi Injection and move stock to clean pasture within 2 weeks of treatment. However, note that lungworm larvae can survive in soil for up to a year or more, and it may be difficult to ensure that the pasture is 'clean'. If clean pastures are unavailable, treatments at 6 weekly intervals should control lungworm until housing.

Eyeworms
The presence of these worms may produce irritation and excessive tear formation in the eye. These tears attract flies which are responsible for the transmission of infection to other cattle. The eyeworms are present throughout the year but transmission from one animal to another, and the annoyance caused by the flies, occurs only during the summer months.

Treatment with Noromectin Multi Injection controls adult eyeworms in cattle at any time of the year.

Lice and Mites
Autumn treatment with Noromectin Multi Injection controls sucking lice, sarcoptic and psoroptic mange mites as infections start to build up. Noromectin Multi Injection may also be used as an aid in the control of biting lice and chorioptic mange mites, but complete elimination may not occur. Treat all animals in contact with each other to prevent cross-infection.

Warbles
The best time to treat is in autumn or early winter, when Noromectin Multi Injection stops the small migrating larvae before they have time to cause serious damage. Treatment with Noromectin Multi Injection kills all stages of warble larvae and may be given whenever convenient for the farmer.

In spring, warbles show as lumps on the backs of previously untreated cattle. Treatment with Noromectin Multi Injection kills these larvae, thus further reducing the population of adult flies for next season.

PRODUCT ADVANTAGES
Low-Volume Injection
Noromectin Injection is highly effective against internal and external parasites at a dose volume of 1 ml per 50 kg bodyweight (0.5 ml per 25 kg). It can be administered quickly and easily.
Broad Spectrum
Noromectin Injection provides broad-spectrum efficacy against roundworms, lungworms in cattle and sheep, eyeworms, warbles, mites and lice in cattle and psoroptic mange and nasal bots of sheep.

Safety
Studies have demonstrated a wide safety margin and the recommended use level had no adverse effect on breeding performance.

PACKAGE INFORMATION
Noromectin Injection is available in four ready-to-use sizes – 50 ml, 100 ml, 250 ml and 500 ml volumes.

Precautions
Cattle must not be treated within 21 days of slaughter for human consumption. Sheep must not be treated within 35 days of slaughter for human consumption. Do not use in cattle or ewes producing milk for human consumption. Do not use in non-lactating diary cows including pregnant heifers within 60 days of calving.

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, 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 ivermectin has been reported in *Teladorsagia* in sheep and goats (also is common in *Haemonchus* in sheep in various parts of the world other than the EU). It has been reported in *Cooperia oncophora* in cattle, in *Teladorsagia* in cattle in New Zealand and Haemonchus in cattle in other parts of the world. Therefore the use of this product should be based on local (regional, farm) epidemiological information about susceptibility of nematodes and recommendations on how to limit further selection for resistance to anthelmintics.

This product is not for intravenous or intramascular use.

Operator Warnings
Do not eat, drink or smoke 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: the product may cause irritation and/or pain at the site of injection

EXCIPIENTS
Glycerol Formal
Polyethylene Glycol

SPECIAL STORAGE CONDITIONS
Protect from light. Do not store above 25°C**.**
Following withdrawal of the first dose, use the product within 28 days.
Discard unused material. Avoid introduction of contamination.
When the container is broached (opened) for the first time, using the in-use shelf-life which is specified on this package leaflet, 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.
This product does not contain any antimicrobial preservative.
Swab septum before removing each dose.
Use a dry sterile needle and syringe.
When using the 250 ml and 500 ml pack sizes, use only automatic syringe equipment. To refill the syringe use of a draw-off needle is recommended to avoid excess broaching of the stopper.
Keep container in outer carton.

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

CONTAINER DISPOSAL
EXTREMELY DANGEROUS TO FISH AND AQUATIC LIFE. Do not contaminate surface water, waterways or ditches with product or used container. Drug containers and any residual contents should be disposed of safely, i.e. by burying in waste ground away from water courses.

NOTE TO USER
Ivermectin belongs to the avermectin [3-AV] class of anthelmintics in the endectocides.
Chemical group of anthelmintic endectocides. [3-AV]

To be supplied only on veterinary prescription.

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Newry, Co. Down, Northern Ireland

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