PARTICULARS TO APPEAR ON <THE OUTER PACKAGE> 50 ml, 100 ml, 250 ml, 500 ml, 1 L CARTON

1. NAME OF THE VETERINARY MEDICINAL PRODUCT
Noromectin 1% w/v Multi Injection Solution for Injection

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES
Ivermectin 1.0% w/v

3. PHARMACEUTICAL FORM
Solution for Injection

4. PACKAGE SIZE
50 ml, 100 ml, 250 ml, 500 ml, 1L

5. TARGET SPECIES
Beef and non-lactating dairy cattle, sheep and pigs

6. INDICATION(S)
For the treatment and control* of gastrointestinal roundworms, lungworms, eyeworms, warbles, mites and sucking lice in beef and non-lactating dairy cattle.

For the treatment and control* of gastrointestinal roundworms, lungworms, nasal bots and psoroptic mange (sheep scab)

For the treatment and control* of gastrointestinal roundworms, lungworms, lice and mange mites in pigs.

*For details see carton and package leaflet.

Cattle
Noromectin Multi Injection is indicated for the treatment and control of the following:
Gastrointestinal roundworms, (adults and fourth stage larvae): *Ostertagia ostertagi (*including inhibited *O. ostertagi), Ostertagia lyrata, Haemonchus placei, Trichostrongylus axei, Trichostrongylus colubriformis, Cooperia oncophora, Cooperia punctata, Cooperia pectinata, Bunostomum phlebotomum, Oesophagostomum radiatum, Strongyloides papillosus* (adult), *Nematodirus helvetianus* (adult), *Nematodirus spathiger* (adult), *and Trichuris spp* (adults)
Lungworms (adult and fourth stage larvae): *Dictyocaulus viviparus*
Eyeworms (adult): *Thelazia* spp
Warbles (parasitic stages): *Hypoderma bovis* and *H. lineatum*
Mange mites: *Sarcoptes scabiei var bovis, Psoroptes bovis*
Sucking lice: *Linognathus vituli, Haematopinus eurysternus* and *Solenopotes capillatus*

Noromectin Multi Injection controls re-infection with the gastrointestinal worms *Haemonchus placei, Cooperia* spp and *Trichostrongylus axei* acquired up to 14 days after treatment, controls re-infection with gastrointestinal worms *Ostertagia ostertagi* and *Oesophagostomum radiatum* acquired up to 21 days after treatment and lungworms (*Dictyocaulus viviparus*) acquired up to 28 days after treatment. Noromectin Multi 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. To obtain optimal benefit from the persistent activity of Noromectin Multi Injection for grazing animals, it is recommended that calves which are set stocked in their first grazing season should be treated 3, 8 and 13 weeks after the day of turnout. Studies have demonstrated that first season grazing calves turned out to pasture in late April or May and treated with Noromectin Multi Injection 3, 8 and 13 weeks after turnout can be protected from parasitic gastro-enteritis and lungworm disease throughout the grazing season, provided they are set stocked, all the calves are included in the programme and that no untreated cattle are added to the pasture.

Sheep

Noromectin Multi Injection is effective for the treatment and control of the following:
Gastrointestinal roundworms (adults and fourth stage larvae): *Teladorsagia circumcincta, O. trifurcata, Haemonchus contortus, Trichostrongylus axei* (adults), *Trichostrongylus colubriformis, Trichostrongylus vitrinus* (adults), *Cooperia curticei, Oesophagostomum venulosum, Oesophagostomum columbianum, Nematodirus filicollis, Chabertia ovina, Trichuris ovis* (adults). Inhibited larval stages and benzimidazole resistant strains of *Haemonchus contortus* and *Ostertagia circumcincta* are also controlled.
Lungworms: *Dictyocaulus filaria* (adults and fourth stage larvae), *Protostrongylus rufescens* (adults).
Mange Mites: *Psoroptes ovis*
Nasal Bot: *Oestrus ovis* (all larval stages)

Pigs

Noromectin Multi Injection is indicated for the treatment and control of the following:
Gastrointestinal worms: *Ascaris suum* (adults and fourth stage larvae), *Hyostrongylus rubidus* (adults and fourth stage larvae), *Oesophagostomum* spp. (adults and fourth stage larvae), *Strongyloides ransomi* (adults and somatic larval stages)
Lungworms: *Metastrongylus* spp (adults)
Lice: *Haematopinus suis*
Mange Mites: *Sarcoptes scabiei* var *suis*
The product may also be used as an aid in the control of adult whipworm (*Trichuris suis*).

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Cattle

Noromectin Multi Injection should be given only by subcutaneous injection at the recommended dosage level of 200 µg per kg bodyweight (1 ml per 50 kg bodyweight).
For example: (Table only included on pack sizes>50 ml)

Bodyweight (kg)	Dose Volume (ml)	Doses per pack
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	
252 to 300	6.0	

Over 300 kg bodyweight, give an additional 1 ml for each additional 50 kg bodyweight.

50 ml: See package leaflet for dosing schedule.

Sheep

Noromectin Multi Injection should be given only by subcutaneous injection in the neck at the recommended dosage level of 200 µg ivermectin per kg bodyweight (0.5 ml per 25 kg bodyweight.)
Use the following dosage schedule: (Table only included on pack sizes>50 ml)

Bodyweight (kg)	Dose Volume (ml)	Doses per pack
Up to 5	0.1	
5.1 to 10	0.2	
10.1 to 15	0.3	
15.1 to 20	0.5	
25.1 to 50	1.0	
50.1 to 75	1.5	
75.1 to 100	2.0	

Noromectin Multi Injection is to be given subcutaneously only. Inject once under the loose skin in the neck. For the treatment and control of sheep scab (Psoroptes ovis) two injections with a seven day interval are required to treat clinical signs of scab and eliminate living mites. Use of a 17 gauge x 1/2 inch (15-20 mm) needle is suggested. Replace with a fresh sterile needle after every 10-12 animals. Injection of wet or dirty animals is not recommended. 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.

50 ml: See package leaflet for dosing schedule.

Pigs

Noromectin Multi Injection should be given only by subcutaneous injection in the neck at the recommended dosage level of 300 µg ivermectin per kg bodyweight (1 ml per 33 kg bodyweight). The use of a 17 gauge x 1/2 inch needle is recommended. Use the following dosage schedule. In pigs, especially those under 16 kg for which less than 0.5 ml of Noromectin is indicated, dosing accuracy is important. The use of a syringe that can accurately deliver 0.1 ml is recommended. For piglets weighing less than 16 kg give 0.1 ml per 3 kg bodyweight.
(Table only included on pack sizes>50 ml)

Bodyweight (kg)	Dose Volume (ml)	Doses per pack

16 to 33	1.0	
34 to 50	1.5	
51 to 66	2.0	
67 to 99	3.0	
100 to 133	4.0	
134 to 166	5.0	
167 to 200	6.0	

Over 200 kg bodyweight, give 1.0 ml per 33 kg bodyweight.

To ensure administration of a correct dose, bodyweight should be determined as accurately as possible; accuracy of the dosing device should be checked.
IMPORTANT: READ PACKAGE LEAFLET BEFORE USE.

8. WITHDRAWAL PERIOD

50 ml: Cattle (meat) – 49 days; Sheep (meat) – 42 days; pigs (meat) – 28 days. Do not use in animals producing milk for human consumption.

Cattle must not be slaughtered for human consumption until 49 days after the last treatment. Do not use in cattle producing milk for human consumption or in non-lactating dairy cows including pregnant heifers within 60 days of calving. Sheep must not be slaughtered for human consumption until 42 days after the last treatment. Do not use in lactating ewes producing milk for human consumption. Pigs must not be slaughtered for human consumption until 28 days after the last treatment.

9. SPECIAL WARNING(S), IF NECESSARY

CONTRAINDICATIONS AND WARNINGS (not included on 50 ml carton)
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. Transitory discomfort and tissue swelling at the site of injection may occur in cattle. Immediately following subcutaneous injection, activity suggesting pain, sometimes intense but usually transient has been observed in some sheep. The product is for subcutaneous administration only and must not be given via other routes.

Do not inject wet or dirty animals
Noromectin Multi Injection is a low-volume product registered for use in cattle, sheep and pigs only. It should not be used in other species as severe adverse reactions including fatalities in dogs, may occur.

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 (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). It has been reported in *Cooperia oncophora* in cattle within the EU, in Teladorsagia in cattle in developed countries such as New Zealand and Haemonchus in cattle outside the EU. 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.

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 accidental self-injection: this product may cause local irritation and/or pain at the injection site.

10. EXPIRY DATE

11. SPECIAL STORAGE CONDITIONS
Protect from sunlight. Do not store above 25°C. Following withdrawal of the first dose, use the product within 28 days. Discard unused material. Avoid the introduction of contamination. This product does not contain an antimicrobial preservative. Swab septum before removing each dose. Use a dry sterile needle and syringe. For 250 ml, 500 ml and 1 litre pack sizes, use of a multiple dose syringe is recommended. To refill the syringe, use of a draw-off needle is recommended to avoid excessive broaching of the stopper. Keep container in outer carton.

12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY
EXTREMELY DANGEROUS TO FISH AND AQUATIC LIFE. Do not contaminate ponds, waterways or ditches with product or used container. Dispose of any unused product and empty containers in accordance with guidance from your local waste regulation authority.

13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE *[Distribution category]*
For animal treatment only.

POM-VPS To be supplied only on veterinary prescription

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"
Keep out of the reach and sight of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER
Norbrook Laboratories Limited, Newry, Co. Down, Northern Ireland.

16. MARKETING AUTHORISATION NUMBER(S)
ManA 2000
Vm 02000/4174

17. MANUFACTURER'S BATCH NUMBER

B.N.:

DOM:

PARTICULARS TO APPEAR ON <THE IMMEDIATE PACKAGE> 50 ml, 100 ml, 250 ml, 500 ml, 1 L LABEL

1. NAME OF THE VETERINARY MEDICINAL PRODUCT
Noromectin 1% w/v Multi Injection Solution for Injection

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES
Ivermectin 1.0% w/v sterile non-aqueous solution of ivermectin for injection.
Ivermectin belongs to the avermectin [3-AV] class of anthelmintic endectocides.

3. PHARMACEUTICAL FORM
Solution for Injection

4. PACKAGE SIZE
50 ml, 100 ml, 250 ml, 500 ml, 1L

5. TARGET SPECIES
cattle, sheep and pigs

6. INDICATION(S)
For the treatment and control* of gastrointestinal roundworms, lungworms, eyeworms, warbles, mites and sucking lice of beef and non-lactating dairy cattle. For the treatment and control* of psoroptic mange (sheep scab), gastrointestinal roundworms, lungworms and nasal bots of sheep. For the treatment and control* of gastrointestinal roundworms, lungworms, lice and mange mites of pigs.

7. METHOD AND ROUTE(S) OF ADMINISTRATION
Cattle: inject subcutaneously at the dose rate of 200 µg/kg (1 ml per 50 kg bodyweight).
Sheep: inject subcutaneously at the dose rate of 200 µg/kg (0.5 ml per 25 kg bodyweight.)
Pigs: inject subcutaneously in the neck at the dose rate of 300 µ/kg bodyweight (1 ml per 33 kg bodyweight).

8. WITHDRAWAL PERIOD
50 ml label:

Cattle (meat) - 49 days;
Sheep (meat) - 42 days;
Pigs (meat) - 28 days.
Do not use in animals producing milk for human consumption.

Cattle must not be treated within 49 days of slaughter for human consumption. Do not use in cattle producing milk for human consumption or in dairy cows including pregnant heifers within 60 days prior to calving. Sheep must not be treated within 42 days of slaughter for human consumption. Do not use in lactating ewes producing milk for human consumption. Pigs must not be treated within 28 days of slaughter for human consumption.

9. SPECIAL WARNING(S), IF NECESSARY
50ml label:
Do not inject wet or dirty animals.

Do not inject wet or dirty animals. This product is not for intravenous or intramuscular use. Noromectin Multi Injection is a low-volume product for use in cattle, sheep and pigs only since severe reactions, including fatalities in dogs, may occur.

Operator Warnings
Do not eat, drink or smoke while handling the product. Direct contact with the skin should be kept to a minimum. Wash hands after use. Take care to avoid accidental self-injection. The product may cause irritation and/or pain at the injection site. This product does not contain any antimicrobial preservative. Swab septum before removing each dose. Use a dry sterile needle and syringe. *** IMPORTANT: READ PACKAGE LEAFLET BEFORE USE.**

10. EXPIRY DATE

11. SPECIAL STORAGE CONDITIONS
Protect from sunlight. Do not store above 25°C. Following withdrawal of the first dose, use the product within 28 days. Discard unused material. Keep container in outer carton. For full special storage conditions see carton and package leaflet.

12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY
Container Disposal: See PACKAGE LEAFLET.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE *[Distribution category]*
For animal treatment only.

POM-VPS To be supplied only on veterinary prescription

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the reach and sight of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER
Norbrook Laboratories Limited, Newry, Co. Down, Northern Ireland.

16. MARKETING AUTHORISATION NUMBER(S)
ManA 2000
Vm 02000/4174

17. MANUFACTURER'S BATCH NUMBER
B.N.:
DOM.:

Date of first broaching: _____

Date to discard: _____

PACKAGE LEAFLET FOR:

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Norbrook Laboratories Limited, Newry, Co. Down, Northern Ireland.

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

NOROMECTIN 1% w/v MULTI INJECTION SOLUTION FOR INJECTION

3. STATEMENT OF THE ACTIVE SUBSTANCE (S) AND OTHER INGREDIENTS

Ivermectin 1.0% w/v 10 mg in 1 ml

4. INDICATION(S)

One low-volume dose of Noromectin Multi Injection controls internal and external parasites that impair the health and productivity. Noromectin Multi 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 avermitilis.* Noromectin Multi Injection is a 1.0% w/v sterile solution of ivermectin. At the rate of 1 ml per 50 kg bodyweight by subcutaneous injection, this formulation will deliver the recommended dosage level of 200 µg ivermectin per kg bodyweight to cattle and/or sheep. At the rate of 1 ml per 33 kg bodyweight by subcutaneous injection, this formulation will deliver the recommended dosage level of 300 µg ivermectin per kg bodyweight to pigs.

Cattle

Noromectin Multi Injection is indicated for the treatment and control of the following species of gastrointestinal roundworms, lungworms, eyeworms, warbles, mites and sucking lice.

Gastrointestinal roundworms (adult and fourth stage larvae):
Ostertagia ostertagi (including inhibited larval stages), *Ostertagia lyrata, Haemonchus placei, Trichostrongylus axei, Trichostrongylus colubriformis*, *Cooperia oncophora, Cooperia punctata, Cooperia pectinata, Bunostomum phlebotomum, Oesophagostomum radiatum, Strongyloides papillosus* (adult), *Nematodirus helvetianus* (adult), *Nematodirus spathiger* (adult), and *Trichuris* spp (adult)
Lungworms (adult and fourth stage larvae): *Dictyocaulus viviparus*
Eyeworms (adult): *Thelazia* spp
Warbles: *Hypoderma bovis* and *Hypoderma lineatum*
Mange Mites: *Psoroptes bovis, Sarcoptes scabiei* var *bovis*

Sucking Lice: *Linognathus vituli, Haematopinus eurysternus,* and *Solenopotes capillatus*
Noromectin Multi 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.

Sheep
Noromectin Multi Injection 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):
Teladorsagia circumcincta, O. trifurcata, *Haemonchus contortus, Trichostrongylus axei* (adults), *Trichostrongylus colubriformis, Trichostrongylus vitrinus* (adults), *Cooperia curticei, Oesophagostomum venulosum, Oesophagostomum columbianum, Nematodirus filicollis*, Chabertia ovina, Trichuris ovis (adults)
Inhibited larval stages and *benzimidazole* resistant strains of *Haemonchus contortus* and *Ostertagia circumcincta* are also controlled.
Lungworms: *Dictyocaulus filaria* (adults and fourth stage larvae), *Protostrongylus rufescens* (adults).
Mange Mites: *Psoroptes ovis*
Nasal Bot: *Oestrus ovis* (all larval stages)

Pigs
Noromectin Multi Injection is indicated for the treatment and control of the harmful species of gastrointestinal roundworms, lungworms, lice and mange mites of pigs.
Gastrointestinal worms:
Ascaris suum (adults and fourth stage larvae)
Hyostrongylus rubidus (adults and fourth stage larvae)
Oesophagostomum spp (adults and fourth stage larvae)
Strongyloides ransomi (adults and somatic larval stages)
Lungworms*: Metastrongylus* spp (adults)
Lice: *Haematopinus suis*
Mange mites: *Sarcoptes scabiei* var suis

Noromectin Multi Injection may also be used as an aid in the control of adult whipworm (*Trichuris suis*).

5. 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, sheep and pigs: 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.

6. ADVERSE REACTIONS

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

7. TARGET SPECIES

For the treatment and control of internal and external parasites of Beef and non-lactating dairy cattle, sheep and pigs.

8. 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.

Cattle

Noromectin Multi Injection should be given only by subcutaneous injection at the recommended dosage level of 200 µg ivermectin per kilogram bodyweight. Each ml contains 10 mg of ivermectin sufficient to treat 50 kg of bodyweight. 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

Noromectin Multi Injection is to be given subcutaneously only. Inject under the loose skin in front of or behind the shoulder. Use of a 17 gauge x ½ 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.

Sheep

Noromectin Multi Injection should be given only by subcutaneous injection at the recommended dosage level of 200 µg ivermectin per kilogram bodyweight (0.5 ml per 25 kg bodyweight). Each ml contains 10 mg ivermectin to treat 50 kg bodyweight. Noromectin Multi Injection is to be given subcutaneously only. Inject once under the loose skin in the neck. For the treatment and control of sheep scab *(Psoroptes ovis)* two injections with a seven day interval are required to treat clinical signs of scab and eliminate living mites. Use of a 17 gauge x 1/2 inch (15-20 mm) needle is suggested. Replace with a fresh sterile needle after every 10-12 animals. Injection of wet or dirty animals is not recommended. 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. 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

Pigs

Noromectin Multi Injection should be given only by subcutaneous injection in the neck at the recommended dosage level of 300 µg ivermectin per kilogram bodyweight (1 ml per 33 kg bodyweight). Use the following dosage schedule. In young pigs, especially those weighing under 16 kg for which less than 0.5 ml of Noromectin is indicated, dosing accuracy is important. The use of a syringe that can accurately deliver 0.1 ml is recommended. For piglets weighing less than 16 kg the product should be given at 0.1 ml per 3 kg.

Bodyweight (kg)	Dose Volume (ml)
17 to 33	1.0
34 to 50	1.5
51 to 66	2.0
67 to 99	3.0
100 to 133	4.0
134 to 166	5.0
167 to 200	6.0

Over 200 kg bodyweight give 1.0 ml per 33 kg bodyweight.

9. 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 systems. 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.

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.

Pigs
Breeding Animals
At the time of initiating any parasite control programme, it is important to treat all breeding animals in the herd. After the initial treatment use Noromectin Multi Injection regularly as follows:

Sows
Treat preferably 7-14 days prior to farrowing, to minimise infection of piglets.

Gilts
Treat 7-14 days prior to service. Treat 7-14 days prior to farrowing.

Boars
Treat at least twice per year. The above programme is a guide for effective parasite control using Noromectin Multi Injection. Alternatively a wide measure of control may be achieved by "total herd treatment" at six-monthly intervals.

Fatteners
All pigs received for fattening should be treated before placement in clean quarters.

Note 1
For effective mange control, care must be taken to prevent reinfestation from exposure to untreated animals or contaminated facilities.

Note 2
Since louse eggs are unaffected by ivermectin and may take up to 3 weeks to hatch, complete elimination may not occur following a single injection.

10. WITHDRAWAL PERIOD(S)
Cattle must not be slaughtered for human consumption until 49 days after the last treatment. 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. Pigs must not be slaughtered for human consumption until 28 days after the last treatment. Sheep must not be slaughtered for human consumption until 42 days after the last treatment. Do not use in lactating ewes producing milk for human consumption.

11. SPECIAL STORAGE PRECAUTIONS

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, 500 ml and 1 litre 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.

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

12. SPECIAL WARNING(S)

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.

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.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

EXTREMELY DANGEROUS TO FISH AND AQUATIC LIFE. Do not contaminate ponds, waterways or ditches with product or used container. Dispose of any unused product and empty containers in accordance with guidance from your local waste regulation authority.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

December 2008

<15. OTHER INFORMATION>

Noromectin Multi Injection is available in five ready-to-use sizes - 50 ml, 100 ml, 250 ml, 500 ml and 1 litre volumes. Not all pack sizes may be marketed.

Legal category POM-VPS To be supplied only on veterinary prescription

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

Vm 02000/4174

Approved: 14/09/2017