

**PARTICULARS TO APPEAR ON THE OUTER PACKAGE**

**50ML PARAMECTIN MULTI INJECTION 1% W/V SOLUTION FOR INJECTION  
FOR CATTLE, SHEEP AND PIGS**

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Paramectin Multi Injection 1% w/v Solution for Injection for Cattle, Sheep and Pigs

**2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES**

Ivermectin 1.0% w/v

Chemical Group of Anthelmintic Endectocides [3-AV]

**3. PHARMACEUTICAL FORM**

Solution for injection

**4. PACKAGE SIZE**

50 ml

**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 of 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 of pigs.

\*For details see carton and package leaflet.

**Cattle**

Paramectin 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*

Paramectin 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.

Paramectin 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**

Paramectin Multi Injection is effective for the treatment and control of the following:

**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*, *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**

Paramectin 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**

### **IMPORTANT: READ PACKAGE LEAFLET BEFORE USE.**

To ensure administration of a correct dose, body weight should be determined as accurately as possible; accuracy of the dosing device should be checked. Do not inject wet or dirty animals.

## **Cattle**

Paramectin 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).

See package leaflet for dosage schedule.

## **Sheep**

Paramectin 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.)

See package leaflet for dosage schedule.

Paramectin 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 scaband

eliminate living mites. 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 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.

### **Pigs**

Paramectin 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 ½ inch needle is recommended.

See package leaflet for dosage schedule. In pigs, especially those under 16 kg for which less than 0.5 ml of Paramectin 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.

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.

Avoid the introduction of contamination.

keep the container in outer carton.

## **8. WITHDRAWAL PERIOD**

### **Cattle :**

Meat: 49 days

Do not use in non-lactating dairy cows including pregnant heifers within 60 days of calving.

### **Pigs:**

Meat: 28days

### **Sheep:**

Meat: 42 days

Do not use in animals producing milk for human consumption

## **9. SPECIAL WARNING(S), IF NECESSARY**

Paramectin 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.

### **User 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 self-injection. The product may cause irritation and/or pain at the injection site.

### **Target species 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, farms) epidemiological information about susceptibility of nematodes and recommendations on how to limit further selection for resistance to anthelmintics

## **10. EXPIRY DATE**

EXP:

D.O.M.:

## **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.

**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 the 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**

**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 SIGHT AND REACH OF CHILDREN**

**15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER**

Norbrook Laboratories Limited

Station Works

Camlough Road

Newry

Co Down

BT35 6JP

**16. MARKETING AUTHORISATION NUMBER(S)**

Vm 02000/4261

**17. MANUFACTURER’S BATCH NUMBER**

BN:

**PARTICULARS TO APPEAR ON THE OUTER PACKAGE**

**100, 250, 500 ML and 1L PARAMECTIN MULTI INJECTION 1% W/V SOLUTION  
FOR INJECTION FOR CATTLE, SHEEP AND PIGS**

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Paramectin Multi Injection 1% w/v Solution for Injection for Cattle, Sheep and Pigs

**2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES**

Ivermectin 1.0% w/v

Chemical Group of Anthelmintic Endectocides [3-AV]

**3. PHARMACEUTICAL FORM**

Solution for injection

**4. PACKAGE SIZE**

100ml/250 ml/500 ml/1 litre

**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 of 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 of pigs.

\*For details see carton and package leaflet.

**Cattle**

Paramectin 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 euryesternus* and *Solenopotes capillatus*

Paramectin 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.

Paramectin 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**

Paramectin Multi Injection is effective for the treatment and control of the following:

**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*, *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**

Paramectin 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**

**IMPORTANT: READ PACKAGE LEAFLET BEFORE USE.**

To ensure administration of a correct dose, body weight should be determined as accurately as possible; accuracy of the dosing device should be checked.

**Cattle**

Paramectin 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:

| <b>Bodyweight (kg)</b> | <b>Dose Volume (ml)</b> | <b>Doses per 100 ml Pack</b> |
|------------------------|-------------------------|------------------------------|
| Up to 50               | 1.0                     | 100                          |
| 51 to 100              | 2.0                     | 50                           |
| 101 to 150             | 3.0                     | 33                           |
| 151 to 200             | 4.0                     | 25                           |
| 201 to 250             | 5.0                     | 20                           |
| 251 to 300             | 6.0                     | 16                           |

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

### **Sheep**

Paramectin 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:

| <b>Bodyweight (kg)</b> | <b>Dose Volume (ml)</b> | <b>Doses per 100 ml Pack</b> |
|------------------------|-------------------------|------------------------------|
| Up to 5                | 0.1                     | 1000                         |
| 5.1 to 10              | 0.2                     | 500                          |
| 10.1 to 15             | 0.3                     | 333                          |
| 15.1 to 25             | 0.5                     | 200                          |
| 25.1 to 50             | 1.0                     | 100                          |
| 50.1 to 75             | 1.5                     | 66                           |
| 75.1 to 100            | 2.0                     | 50                           |

Paramectin 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 ½ 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.

### **Pigs**

Paramectin 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 ½ inch needle is recommended.

Use the following dosage schedule. In pigs, especially those under 16 kg for which less than 0.5 ml of Paramectin 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.

| <b>Bodyweight (kg)</b> | <b>Dose Volume (ml)</b> | <b>Doses per 100 ml Pack</b> |
|------------------------|-------------------------|------------------------------|
| 16 to 33               | 1.0                     | 100                          |
| 34 to 50               | 1.5                     | 66                           |
| 51 to 66               | 2.0                     | 50                           |
| 67 to 99               | 3.0                     | 33                           |
| 100 to 133             | 4.0                     | 25                           |
| 134 to 166             | 5.0                     | 20                           |
| 167 to 200             | 6.0                     | 16                           |

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

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.

Avoid the introduction of contamination.

Keep container in outer carton.

## **8. WITHDRAWAL PERIOD**

### **Cattle :**

Meat and offal: 49 days

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:**

Meat and offal: 28days

### **Sheep:**

Meat and offal: 42 days

Do not use in lactating ewes producing milk for human consumption.

## **9. SPECIAL WARNING(S), IF NECESSARY**

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.

Paramectin 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.

### **User 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 self-injection. The product may cause irritation and/or pain at the injection site.

### **Target species 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, farms) epidemiological information about susceptibility of nematodes and recommendations on how to limit further selection for resistance to anthelmintics.

## **10. EXPIRY DATE**

EXP:

D.O.M.:

## **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.

## **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 the 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**

### **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 SIGHT AND REACH OF CHILDREN**

## **15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER**

Norbrook Laboratories Limited

Station Works

Camlough Road

Newry

Co Down

BT35 6JP

**16. MARKETING AUTHORISATION NUMBER(S)**

Vm 02000/4261

**17. MANUFACTURER'S BATCH NUMBER**

BN:

**PARTICULARS TO APPEAR ON IMMEDIATE PACKAGE**

**50ml PARAMECTIN MULTI INJECTION 1% W/V SOLUTION FOR INJECTION  
FOR CATTLE, SHEEP AND PIGS**

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Paramectin Multi Injection 1% w/v Solution for Injection for Cattle, Sheep and Pigs

**2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES**

Ivermectin                      1.0% w/v

Ivermectin belongs to the avermectin [3-AV] class of anthelmintic endectocides.

**3. PHARMACEUTICAL FORM**

Solution for injection.

**4. PACKAGE SIZE**

50 ml

**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 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.

**\* IMPORTANT: READ PACKAGE LEAFLET BEFORE USE.**

**7. METHOD AND ROUTE(S) OF ADMINISTRATION**

This product does not contain any antimicrobial preservative. Swap septum before removing each dose. Use a dry sterile needle and syringe.

Keep container in outer carton.

To ensure administration of a correct dose, body weight should be determined as accurately as possible; accuracy of the dosing device should be checked.

Cattle: inject subcutaneously at the dose rate of 200 µg/kg (1 ml per 50 kg bodyweight).

Sheep: inject subcutaneously to 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 µg/kg bodyweight (1 ml per 33 kg bodyweight).

## **8. WITHDRAWAL PERIOD**

Cattle (meat) – 49 days; Sheep (meat) – 42 days; Pigs (meat) – 28 days.

Do not use in animals producing milk for human consumption.

Do not use in non-lactating dairy cows including pregnant heifers within 60 days of calving.

## **9. SPECIAL WARNING(S), IF NECESSARY**

Do not inject wet or dirty animals.

### **User 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 self-injection; the product may cause local irritation and/or pain at the injection site.

## **10. EXPIRY DATE**

EXP:

DOM:

## **11. 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.

Date of first broaching: --/--/--

Date to discard --/--/--



**12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY**

See PACKAGE LEAFLET.

**13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE**

**FOR ANIMAL TREATMENT ONLY**

POM-VPS

To be supplied only on veterinary prescription

**UK AUTHORISED VETERINARY MEDICINAL PRODUCT**

**14. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”**

**KEEP OUT OF THE SIGHT AND REACH OF CHILDREN**

**15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER**

Norbrook Laboratories Limited

Station Works

Camlough Road

Newry

Co Down

BT35 6JP

**16. MARKETING AUTHORISATION NUMBER(S)**

Vm 02000/4261

**17. MANUFACTURER’S BATCH NUMBER**

BN:

**PARTICULARS TO APPEAR ON IMMEDIATE PACKAGE**

**100, 250, 500 ml and 1L PARAMECTIN MULTI INJECTION 1% W/V SOLUTION  
FOR INJECTION FOR CATTLE, SHEEP AND PIGS**

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Paramectin Multi Injection 1% w/v Solution for Injection for Cattle, Sheep and Pigs

**2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES**

Ivermectin                      1.0% w/v

Ivermectin belongs to the avermectin [3-AV] class of anthelmintic endectocides.

**3. PHARMACEUTICAL FORM**

Solution for injection.

**4. PACKAGE SIZE**

100 ml, 250 ml, 500 ml, 1 litre

**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 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.

**\* IMPORTANT: READ PACKAGE LEAFLET BEFORE USE.**

**7. METHOD AND ROUTE(S) OF ADMINISTRATION**

This product does not contain any antimicrobial preservative. Swap septum before removing each dose. Use a dry sterile needle and syringe.

Keep container in outer carton.

To ensure administration of a correct dose, body weight should be determined as accurately as possible; accuracy of the dosing device should be checked.

Cattle: inject subcutaneously at the dose rate of 200 µg/kg (1 ml per 50 kg bodyweight).

Sheep: inject subcutaneously to 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 µg/kg bodyweight (1 ml per 33 kg bodyweight).

## **8. WITHDRAWAL PERIOD**

### **Cattle :**

Meat and offal: 49 days

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:**

Meat and offal: 28days

### **Sheep:**

Meat and offal: 42 days

Do not use in lactating ewes producing milk for human consumption

## **9. SPECIAL WARNING(S), IF NECESSARY**

Do not inject wet or dirty animals.

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

### **User 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 self-injection; the product may cause local irritation and/or pain at the injection site.

## 10. EXPIRY DATE

EXP:

DOM:

## 11. 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.

Date of first broaching:--/--/--

Date to discard --/--/--

## 12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

See PACKAGE LEAFLET.

## 13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE

### FOR ANIMAL TREATMENT ONLY

POM-VPS

To be supplied only on veterinary prescription

## UK AUTHORISED VETERINARY MEDICINAL PRODUCT

## 14. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

### KEEP OUT OF THE SIGHT AND REACH OF CHILDREN

## 15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Norbrook Laboratories Limited

Station Works

Camlough Road

Newry

Co Down

BT35 6JP

## 16. MARKETING AUTHORISATION NUMBER(S)

Vm 02000/4261

**17. MANUFACTURER'S BATCH NUMBER**

BN:

**PACKAGE LEAFLET FOR:PARAMECTIN MULTI INJECTION 1%W/V SOLUTION FOR INJECTION FOR CATTLE, SHEEP AND PIGS**

**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**

Paramectin Multi Injection 1% w/v Solution for Injection for Cattle, Sheep and Pigs.

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

Ivermectin 1.0% w/v

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

**4. INDICATION(S)**

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

**Cattle**

Paramectin 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*

Paramectin 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**

Paramectin 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):

*Ostertagia 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**

Paramectin 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*

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

### **Persistent activity**

When cattle have to graze on pasture contaminated with infective larvae of cattle nematodes, treatment with Paramectin Multi Injection at the recommended dose rate controls re-infection with *Haemonchus placei*, *Cooperia* spp and *Trichostrongylus axei* acquired up to 14 days after treatment, *Ostertagia ostertagi* and *Oesophagostomum radiatum* acquired up to 21 days after treatment and *Dictyocaulus viviparus* acquired up to 28 days after treatment.

## **5. CONTRAINDICATIONS**

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

Paramectin 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.

## **6. ADVERSE REACTIONS**

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.

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

## **7. TARGET SPECIES**

Beef and non-lactating dairy cattle, sheep and pigs.

## **8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION**

This product does not contain an antimicrobial preservative. Swab septum before removing each dose. Use a dry sterile needle and syringe. For 250 ml, 500ml 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.

Avoid introduction of contamination.

Keep container in outer carton



To ensure administration of a correct dose, body weight should be determined as accurately as possible; accuracy of the dosing device should be checked.

### **Cattle**

Paramectin 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.

| <b>Bodyweight (kg)</b> | <b>Dose Volume (ml)</b> |
|------------------------|-------------------------|
| 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                    |

Paramectin 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**

Paramectin 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.

Paramectin 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 ½ 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:

| <b>Bodyweight (kg)</b> | <b>Dose Volume (ml)</b> |
|------------------------|-------------------------|
| 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**

Paramectin 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 Paramectin 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.

| <b>Bodyweight (kg)</b> | <b>Dose Volume (ml)</b> |
|------------------------|-------------------------|
|------------------------|-------------------------|

|            |     |
|------------|-----|
| 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**

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.

The suggested dosing programme has been developed to make the best use of the properties of Paramectin 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 Paramectin 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.

#### **Lungworm**

Outbreaks of husk (hoose) are most common in summer and autumn.

Where outbreaks of husk occur, treat promptly with Paramectin 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'

#### **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.

### **Lice and Mites**

Paramectin Multi Injection controls sucking lice, sarcoptic and psoroptic mange mites. Paramectin 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**

Treatment with Paramectin Multi Injection kills all stages of warble larvae and may be given whenever convenient for the farmer. A suitable dosing programme should be established by a veterinary professional.

### **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 Paramectin 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 Paramectin Multi Injection.

#### **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 :**

Meat and offal: 49 days

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:**

Meat and offal: 28days

### **Sheep:**

Meat and offal: 42 days

Do not use in lactating ewes producing milk for human consumption

## **11. SPECIAL STORAGE PRECAUTIONS**

### **PHARMACEUTICAL 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.

## **12. SPECIAL WARNING(S)**

It should be noted that single doses of 4.0 mg/kg ivermectin (20 times the recommended dosage) administered subcutaneously to cattle and sheep results in ataxia and depression. No antidote has been identified. Symptomatic treatment may be beneficial.

Ivermectin has a recognised wide safety margin and is known to be safe in all ages of swine. It has no adverse effects on fertility in sows or breeding performance of boars.

Clinical signs of ivermectin toxicity in swine include tremors, bilateral mydriasis and recumbency with some biochemical abnormalities including a transient depression of serum iron. Such changes were only observed when ivermectin was administered subcutaneously at a dose of 30 mg/kg (100 times the normal therapeutic dose).

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.

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, farms) epidemiological information about susceptibility of nematodes and recommendations on how to limit further selection for resistance to anthelmintics.

### **User 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 the 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 2010

### **15. OTHER INFORMATION>**

One low-volume dose of Paramectin Multi Injection controls internal and external parasites that impair the health and productivity.

### **PRODUCT DESCRIPTION**

Paramectin 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*.

Paramectin 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.

### **MODE OF ACTION**

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.

### **PACKAGE INFORMATION**

Paramectin 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

FOR ANIMAL TREATMENT ONLY

**UK AUTHORISED VETERINARY MEDICINAL PRODUCT**

**VM:02000/4261**

**Approved: 14/09/2017**

A handwritten signature in black ink, appearing to read 'J. King', is positioned below the approval date.