

**PARTICULARS TO APPEAR ON THE OUTER PACKAGE {Carton box Flat-bottle}**

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

Panacur 10% oral suspension

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

Fenbendazole

**3. PHARMACEUTICAL FORM**

Oral suspension containing 100 mg fenbendazole per ml.

**4. PACKAGE SIZE**

1 Litre

2 Litres

5 Litres

10 Litres

1 Litre

1000 doses for 20 kg lambs, 400 doses for 50 kg ewes

66 doses for 200 kg cattle, 22 doses for 600 kg horses

2 Litre

2000 doses for 20 kg lambs, 800 doses for 50 kg ewes

133 doses for 200 kg cattle, 44 doses for 600 kg horses

5 Litre

5000 doses for 20 kg lambs, 2000 doses for 50 kg ewes

333 doses for 200 kg cattle, 111 doses for 600 kg horses

10 Litre

10000 doses for 20 kg lambs, 4000 doses for 50 kg ewes

666 doses for 200 kg cattle, 222 doses for 600 kg horses

**5. TARGET SPECIES**

Cattle, sheep and horse wormer.

## 6. INDICATION(S)

For the treatment and control of gastro-intestinal roundworm infections in cattle, sheep and horses and of lungworm and tapeworm infections in cattle and sheep.

### USES

Panacur 10 % suspension is a broad spectrum anthelmintic for the control of all major benzimidazole-susceptible species of gastro-intestinal roundworms, including *Ostertagia* spp., *Teldorsagia* spp. and *Nematodirus* spp., and lungworms affecting cattle and sheep. It is effective against the adult and immature stages of gastro-intestinal roundworms and lungworms and also kills roundworm eggs. Panacur 10 % suspension is also usually effective against Type II winter ostertagiasis in cattle and against *Moniezia* spp. of tapeworm in cattle and sheep. In horses and other equines,

Panacur 10 % suspension is effective against benzimidazole-susceptible large and small strongyles, ascarids, *Oxyuris* spp. and *Strongyloides* spp.

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

### DOSAGE AND ADMINISTRATION

For oral administration only. Shake container well before use.

Cattle and Horses: 1ml per 13 kg bodyweight (7.5 mg fenbendazole per kg bodyweight) to be given orally (see table). For horses, mix the product with grain or concentrate feed and give the full dose as one administration. Pregnant mares and foals may be treated safely with fenbendazole at therapeutic levels. For the treatment of migrating larval and tissue stages of large strongyles and encysted stages of small strongyles in horses, the dose should be repeated daily for five days. Sheep: 0.5 ml per 10 kg bodyweight (5 mg fenbendazole per kg bodyweight) to be given orally (see table).

A dosing scheme per target species as well as guidance regarding the number of doses per pack size is provided on the carton box.

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

Treatment should be repeated when reinfestation occurs.

## 8. WITHDRAWAL PERIOD

Do not use in horses and other equines intended for human consumption.

Withdrawal periods: Animals must not be slaughtered for human consumption during treatment.

Cattle may be slaughtered for human consumption only after 12 days from the last treatment. Sheep may be slaughtered for human consumption only after 15 days from the last treatment. Milk from treated animals must not be taken for human consumption during treatment. Milk from treated cows may be taken for human consumption only after 5 days from the last treatment. Milk from treated sheep may be taken for human consumption only after 7 days from the last treatment.

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

### CONTRA-INDICATIONS AND WARNINGS

**Operator warnings:** Direct contact with the skin should be kept to a minimum. Wear suitable protective clothing including impermeable rubber gloves. Wash hands after use.

**Disposal advice:** Dangerous to aquatic life. Dispose of any unused product and empty containers in accordance with guidance from your local waste regulation authority. Do not contaminate ponds, waterways or ditches with product or used containers.

**Other warnings:** Intensive use or misuse of anthelmintics can give rise to resistance. To reduce this risk, discuss dosing programmes with your veterinary surgeon.

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.
  - Under dosing, 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 benzimidazoles (which include fenbendazole) has been reported in *Teladorsagia*, *Haemonchus*, *Cooperia* and *Trichostrongylus* species in small ruminants in a number of countries, including 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.

Resistance to fenbendazole has been reported in cyathostomes in horses. 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.

**Overdose:** Benzimidazoles have a high margin of safety. No specific overdose symptoms are known. No specific actions required.

## 10. EXPIRY DATE

EXP END OF: {month/year}

## 11. SPECIAL STORAGE CONDITIONS

Storage: Do not store above 25°C. Do not freeze. Protect from frost.

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

Dangerous to aquatic life. Dispose of any unused product and empty containers in accordance with guidance from your local waste regulation authority. Do not contaminate ponds, waterways or ditches with product or used containers.

## **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 |
|---------|

## **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**

MA Holder:

MSD Animal Health UK Ltd.  
Walton Manor  
Walton  
Milton Keynes  
MK7 7AJ

Distributed in Northern Ireland by  
Intervet Ireland Ltd  
Magna Drive, Magna Business Park, Citywest Road, Dublin 24

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

Vm 01708/4435

## **17. MANUFACTURER’S BATCH NUMBER**

BN: {number}

Do not mix with other products.

Instructions for use with automatic dosing equipment (e.g. Panacur® Drencher):

1. Remove the product container from the carton and shake well.
2. Attach plastic hook through a hole at the base of the bottle and tie strap through diagonally opposite hole at the top, making adjustments as necessary to allow the bottle to hang comfortably on the operator’s back.

3. With the product container in the upright position, remove the plain cap and pierce seal with the nozzle cap provided.
4. Screw nozzle cap tightly onto the bottle and firmly attach tube from the automatic dosing equipment to the nozzle. Class of anthelmintic: 1-BZ
5. Hang the bottle in the inverted position on the operator's back and carefully prime the gun.

Part used packs may be kept. The nozzle cap should be replaced by the plain cap.  
To be supplied only on veterinary prescription.

**MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING**  
**UNITS {Front label Flat-bottle}**

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

Panacur 10% oral suspension

**2. QUANTITY OF THE ACTIVE SUBSTANCE(S)**

Fenbendazole

**3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES**

**1 Litre**

1000 doses for 20 kg lambs  
400 doses for 50 kg ewes  
66 doses for 200 kg cattle  
22 doses for 600 kg horses

**2 Litre**

2000 doses for 20 kg lambs  
800 doses for 50 kg ewes  
133 doses for 200 kg cattle  
44 doses for 600 kg horses

**5 Litre**

5000 doses for 20 kg lambs  
2000 doses for 50 kg ewes  
333 doses for 200 kg cattle  
111 doses for 600 kg horses

**10 Litre**

10000 doses for 20 kg lambs  
4000 doses for 50 kg ewes  
666 doses for 200 kg cattle  
222 doses for 600 kg horses

**1 Litre**

**2 Litres**

**5 Litres**

**10 Litres**

**4.ROUTE(S) OF ADMINISTRATION**

Oral suspension.

**5.WITHDRAWAL PERIOD**

**6.BATCH NUMBER**

**7.EXPIRY DATE**

**8.THE WORDS “FOR ANIMAL TREATMENT ONLY”**

Cattle, sheep and horse wormer

**MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING  
UNITS {Back label Flat-bottle}**

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

Panacur 10% oral suspension

Panacur 10% is an oral suspension containing 100 mg fenbendazole per ml.

**2. QUANTITY OF THE ACTIVE SUBSTANCE(S)**

Fenbendazole

**3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES**

|                              |                                                                                                                                         |       |       |       |       |       |
|------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------|-------|-------|-------|-------|-------|
|                              | Practical Dosage Recommendations<br>Cattle and horses above 400kg should be given a further 5ml<br>for each additional 65kg bodyweight) |       |       |       |       |       |
| Weight of cattle /<br>horses | 65kg                                                                                                                                    | 135kg | 200kg | 265kg | 335kg | 400kg |
| Dose                         | 5ml                                                                                                                                     | 10ml  | 15ml  | 20ml  | 25ml  | 30ml  |

Sheep: 0.5ml per 10kg bodyweight (5mg Fenbendazole per kg bodyweight) to be given orally.

|                 |                                                                                                                               |      |       |      |       |      |
|-----------------|-------------------------------------------------------------------------------------------------------------------------------|------|-------|------|-------|------|
|                 | Practical Dosage Recommendations<br>(Sheep above 60kg should be given a further 0.5ml for each<br>additional 10kg bodyweight) |      |       |      |       |      |
| Weight of sheep | 10kg                                                                                                                          | 20kg | 30kg  | 40kg | 50kg  | 60kg |
| Dose            | 0.5ml                                                                                                                         | 1ml  | 1.5ml | 2ml  | 2.5ml | 3ml  |

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

**4. ROUTE(S) OF ADMINISTRATION**

Oral suspension.

**5. WITHDRAWAL PERIOD**

**6. BATCH NUMBER**

BN: {number}

**7. EXPIRY DATE**

EXP END OF: {month/year}



## 8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

### USES

Broad spectrum anthelmintic for the treatment and control of gastro-intestinal roundworm infections in cattle, sheep and horses and of lungworm and tapeworm infections in cattle and sheep.

### DOSAGE AND ADMINISTRATION

For oral administration only. Shake container well before use.

**Cattle and Horses:** 1ml per 13 kg bodyweight (7.5 mg fenbendazole per kg bodyweight) to be given orally.

For horses, mix the product with grain or concentrate feed and give the full dose as one administration.

### CONTRA-INDICATIONS AND WARNINGS

Do not use in horses and other equines intended for human consumption.

**Withdrawal periods:** Animals must not be slaughtered for human consumption during treatment.

Cattle may be slaughtered for human consumption only after 12 days from the last treatment.

Sheep may be slaughtered for human consumption only after 15 days from the last treatment.

Milk from treated animals must not be taken for human consumption during treatment.

Milk from treated cows may be taken for human consumption only after 5 days from the last treatment.

Milk from treated sheep may be taken for human consumption only after 7 days from the last treatment.

**Operator warnings:** Direct contact with the skin should be kept to a minimum. Wear suitable protective clothing including impermeable rubber gloves. Wash hands after use.

**Disposal advice:** Dangerous to aquatic life. Dispose of any unused product and empty containers in accordance with guidance from your local waste regulation authority. Do not contaminate ponds, waterways or ditches with product or used containers.

**Other warnings:** Intensive use or misuse of anthelmintics can give rise to resistance, see carton text. To reduce this risk, discuss dosing programmes with your veterinary surgeon. Do not mix with other products.

**Overdose:** Benzimidazoles have a high margin of safety. No specific overdose symptoms are known. No specific actions required.

**Keep out of the sight and reach of children.**

**Storage:** Do not store above 25°C. Do not freeze.

Protect from frost. Keep container in its outer carton.

For further information on uses and dosing, please refer to the carton.

Legal category: **POM-VPS** To be supplied only on veterinary prescription. Vm 01708/4435

MA Holder:  
MSD Animal Health UK Ltd.  
Walton Manor  
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Milton Keynes  
MK7 7AJ

Distributed in Northern Ireland by  
Intervet Ireland Ltd  
Magna Drive, Magna Business Park  
Citywest Road, Dublin 24

Cattle, sheep and horse wormer

**MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS**

Front label, 1 Litre and 2.5 Litre Flexi-bottle

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

Panacur 10% oral suspension  
Fenbendazole

**2. QUANTITY OF THE ACTIVE SUBSTANCE(S)**

Panacur 10% is an oral suspension containing 100 mg fenbendazole per ml.

**3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES**

1 Litre

2.5 Litres

1 Litre:

1000 doses for 20 kg lambs  
400 doses for 50 kg ewes  
66 doses for 200 kg cattle  
22 doses for 600 kg horses

2.5 Litres:

2500 doses for 20 kg lambs  
1000 doses for 50 kg ewes  
166 doses for 200 kg cattle  
55 doses for 600 kg horses

**4. ROUTE(S) OF ADMINISTRATION**

Oral suspension.

**5. WITHDRAWAL PERIOD**

Read the pull-out leaflet before use.

**6. BATCH NUMBER**

|                       |
|-----------------------|
| <b>7. EXPIRY DATE</b> |
|-----------------------|

|                                                 |
|-------------------------------------------------|
| <b>8. THE WORDS “FOR ANIMAL TREATMENT ONLY”</b> |
|-------------------------------------------------|

For animal treatment only. Cattle, sheep and horse wormer.

## **PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE**

**1 Litre and 2.5 Litre Flexi-bottle**

BACK LABEL

**{CONCERTINA LABEL<sup>1</sup>. – Base Label and Top Label} package leaflet inner pages of the concertina label to be as per package leaflet text below.**

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

Panacur 10% oral suspension

Fenbendazole

### **2. STATEMENT OF ACTIVE SUBSTANCES**

Panacur 10% is an oral suspension containing 100 mg fenbendazole per ml.

### **3. PHARMACEUTICAL FORM**

Oral suspension

### **4. PACKAGE SIZE**

1 Litre

2.5 Litres

### **5. TARGET SPECIES**

Cattle, sheep and horses.

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<sup>1</sup> For concertina labels, the immediate label template heading requirements must begin and end the proposal. The leaflet requirements should go in-between. The immediate label must be stuck to the container and be replicated on the outer facing part of the concertina label.

**6. INDICATION(S)**

**Read the pull-out leaflet before use.**

Broad spectrum anthelmintic for the treatment and control of gastro-intestinal roundworm infections in cattle, sheep and horses and of lungworm and tapeworm infections in cattle and sheep.

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

**Read the pull-out leaflet before use.**

**8. WITHDRAWAL PERIOD(S)**

**Withdrawal Periods:** Cattle - Meat: 12 Days

Milk : 5 Days

Sheep - Meat: 15 Days

Milk : 7 Days

Do not use in horses and other equines intended for human consumption.

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

**Read the pull-out leaflet before use.**

**10. EXPIRY DATE**

Exp end of:

**11. SPECIAL STORAGE CONDITIONS**

Do not store above 25°C. Do not freeze.

Protect from frost.

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

**Read the pull-out leaflet before use.**

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

POM-VPS

To be supplied only on veterinary prescription.

For animal treatment only.

Class of anthelmintic:

1-BZ

**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**

**MA Holder:**

MSD Animal Health UK Ltd.  
Walton Manor  
Walton  
Milton Keynes  
MK7 7AJ

**Distributor in Northern Ireland:**

Intervet Ireland Ltd.

Magna Drive  
Magna Business Park  
Citywest Road  
Dublin 24

|                                               |
|-----------------------------------------------|
| <b>16. MARKETING AUTHORISATION NUMBER (S)</b> |
|-----------------------------------------------|

Vm 01708/4435

|                                        |
|----------------------------------------|
| <b>17. MANUFACTURER'S BATCH NUMBER</b> |
|----------------------------------------|

BN:



**PACKAGE LEAFLET FOR:**  
**Panacur 10% oral suspension**

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

Marketing Authorisation Holder:

MSD Animal Health UK Ltd.  
Walton Manor  
Walton  
Milton Keynes  
Buckinghamshire  
MK7 7AJ

Manufacturer responsible for batch release:

Intervet Productions S.A.  
Rue de Lyons  
27460 Igoville  
France

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

Panacur 10% oral suspension  
Fenbendazole

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

Panacur 10% is an oral suspension containing 100 mg fenbendazole per ml.  
Clear colourless or virtually colourless oral suspension.

**4. INDICATION(S)**

For the treatment and control of gastro-intestinal roundworm infections in cattle, sheep and horses and of lungworm and tapeworm infections in cattle and sheep.

Panacur 10% oral suspension is a broad spectrum anthelmintic for the control of all major benzimidazole-susceptible species of gastro-intestinal roundworms, including *Ostertagia* spp., *Teladorsagia* spp. and *Nematodirus* spp. and lungworms affecting cattle and sheep. It is effective against the adult and immature stages of gastro-intestinal roundworms and lungworms and also kills roundworm eggs. Panacur 10% oral suspension is also usually effective against Type II winter ostertagiasis

in cattle and against *Moniezia* spp. of tapeworm in cattle and sheep. In horses and other equines, Panacur 10% oral suspension is effective against benzimidazole-

susceptible large and small strongyles, ascarids, *Oxyuris* spp. and *Strongyloides* spp.

## 5. CONTRAINDICATIONS

Do not use in horses and other equines intended for human consumption.

Fenbendazole as a medicated liquid feed should not be used in the treatment of clinical infestations in cattle and sheep.

## 6. ADVERSE REACTIONS

None known.

If you notice any side effects or you think that the medicine has not worked, please inform your veterinary surgeon.

## 7. TARGET SPECIES

Cattle, sheep, horses and other equines.

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

**For oral administration only.** Shake container before use.

**Cattle and Horses:** 1 ml per 13 kg bodyweight (7.5 mg fenbendazole per kg bodyweight) to be given orally (see table). For horses, mix the product with grain or concentrate feed and give the full dose as one administration.

|                           | Practical Dosage Recommendations<br>(Cattle and horses above 400 kg should be given a further 5 ml for each additional 65 kg bodyweight) |        |        |        |        |        |
|---------------------------|------------------------------------------------------------------------------------------------------------------------------------------|--------|--------|--------|--------|--------|
| Weight of cattle / horses | 65 kg                                                                                                                                    | 135 kg | 200 kg | 265 kg | 335 kg | 400 kg |
| Dose                      | 5 ml                                                                                                                                     | 10 ml  | 15 ml  | 20 ml  | 25 ml  | 30 ml  |

### Horses:

**Recommended dosage programme:** Horses should be routinely wormed with the single dose regimen every 6-8 weeks.

**Five day course:** For the treatment and control of migrating and tissue larval stages of large strongyles, encysted mucosal 3<sup>rd</sup> and 4<sup>th</sup> stage small strongyle larvae and encysted inhibited 3<sup>rd</sup> stage small strongyle larvae in the mucosa administer 5 ml per 64 kg bodyweight daily for 5 days (7.5 mg fenbendazole per kg bodyweight daily for 5 days).

**Single dose treatment:** For the treatment and control of encysted mucosal stages of small strongyles administer 3 ml per 10 kg bodyweight (30 mg fenbendazole per kg bodyweight).

For the treatment and control of migrating and tissue stages of large strongyles

administer 6 ml per 10 kg bodyweight (60 mg fenbendazole per kg body weight).  
For the treatment of diarrhoea cause by *Strongyloides westeri* in two to three week old sucking foals administer 5 ml per 10 kg body weight (50 mg fenbendazole per kg bodyweight).

**Sheep:** 0.5 ml per 10 kg bodyweight (5 mg fenbendazole per kg bodyweight) to be given orally (see table).

|                 | Practical Dosage Recommendations<br>(Sheep above 60 kg should be given a further 0.5 ml for each additional 10 kg bodyweight) |       |        |       |        |       |
|-----------------|-------------------------------------------------------------------------------------------------------------------------------|-------|--------|-------|--------|-------|
| Weight of sheep | 10 kg                                                                                                                         | 20 kg | 30 kg  | 40 kg | 50 kg  | 60 kg |
| Dose            | 0.5 ml                                                                                                                        | 1 ml  | 1.5 ml | 2 ml  | 2.5 ml | 3 ml  |

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

Treatment should be repeated when reinfestation occurs.

Do not mix with other products.

## 9. ADVICE ON CORRECT ADMINISTRATION

The product is best administered to cattle with the Panacur 20 ml Automatic Drencher and to sheep with the 5 ml Sheep Drencher, but other standard dosing guns or drenching equipment may also be used.

## 10. WITHDRAWAL PERIOD(S)

Cattle – Meat: 12 Days

Milk: 5 Days

Sheep – Meat: 15 Days

Milk: 7 Days

Not to be used in horses intended for human consumption. Treated horses may never be slaughtered for human consumption. The horse must have been declared as not intended for human consumption under national horse passport legislation.

## 11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

Do not store above 25°C. Do not freeze. Protect from frost.

## 12. SPECIAL WARNING(S)

When administered by divided dosage in the form of liquid feed, the product may not be effective against *Strongyloides* spp. and *Trichuris* spp. in cattle and *Strongyloides* spp., *Dictyocaulus* spp. and *Bunostomum* spp. in sheep.

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.
- Under dosing, which may be due to underestimation of bodyweight, 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 benzimidazoles (which include fenbendazole) has been reported in *Teladorsagia* spp., *Haemonchus* spp., *Cooperia* spp. and *Trichostrongylus* spp. in small ruminants in a number of countries, including 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.

Resistance to fenbendazole has been reported in cyathostomes in horses. 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.

#### Special precautions for use in animals:

Assess body weight as accurately as possible before calculating the dosage. Intensive use or misuse of anthelmintic can give rise to resistance. To reduce this risk, dosing programmes should be discussed with your veterinary surgeon.

#### Special precautions to be taken by the person administering the veterinary medicinal product to animals:

Direct contact with the skin should be kept to a minimum. Wear suitable protective clothing including impermeable rubber gloves.  
Wash hands after use.

#### Pregnancy and lactation:

The product can be administered to pregnant animals. Pregnant mares and young foals may also be safely treated with fenbendazole at the therapeutic dosage levels.

#### Interaction with other medicinal products and other forms of interaction:

None known.

#### Overdose (symptoms, emergency procedures, antidotes):

Benzimidazoles have a high margin of safety. No specific overdose symptoms are known. No specific actions required.

Incompatibilities:

None known.

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

Dangerous to aquatic life. Dispose of any unused product and empty containers in accordance with guidance from your local waste regulation authority. Do not contaminate ponds, waterways or ditches with product or used containers.

**14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED**

May 2022

**15. OTHER INFORMATION**

For animal treatment only.

Pack sizes:

1, 2, 5 or 10 litre multidose containers. Container: opaque white, high density polyethylene flat-bottle. Closure: Tamper proof aluminium foil seal with polypropylene screw cap.

1 litre or 2.5 litre multidose containers. Container: opaque white, high density polyethylene flexi-bottle with polypropylene screw cap.

Not all pack sizes may be marketed.

Class of anthelmintic:

1-BZ

Legal category: POM-VPS

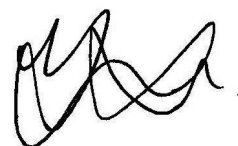
To be supplied only on veterinary prescription.

Vm 01708/4435

**Distributor in Northern Ireland**

Intervet Ireland Ltd.

Magna Drive  
Magna Business Park  
Citywest Road  
Dublin 24



Approved: 29 July 2022