#### PARTICULARS TO APPEAR ON THE OUTER PACKAGE

{CARTON BOX/ 100 x 1 g}

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

Panacur Granules 222 mg/g.

#### 2. STATEMENT OF ACTIVE SUBSTANCES

Panacur Granules contains 222.22 mg/g fenbendazole.

#### 3. PHARMACEUTICAL FORM

A white granulate formulation of fenbendazole as a ready to use oral anthelmintic.

#### 4. PACKAGE SIZE

100 x 1 g sachets

#### **5. TARGET SPECIES**

Cats, dogs, kittens and puppies.

#### 6. INDICATION(S)

Wormer for cats, dogs, kittens and puppies.

- For the treatment of adult dogs and cats infected with gastro-intestinal roundworms and tapeworms including *Toxocara canis*, *Toxocara cati*, *Toxascaris leonina*, *Ancylostoma* spp., *Trichuris* spp., *Uncinaria* spp., and *Taenia* spp.
- For the treatment of weaned puppies and kittens infected with gastrointestinal roundworms.
- For the treatment of pregnant bitches, to reduce pre-natal infection with *Toxocara* canis and the transfer of *T. canis* and *Ancylostoma caninum* to the pups via milk.
- For the treatment of adult dogs and puppies with protozoa Giardia spp.
- Also effective against lungworms *Oslerus (Filaroides) osleri* in dogs and *Aelurostrongylus abstrusus* in cats.

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

Mixes into feed

2 kg dose at 100 mg/kg bodyweight

4 kg dose at 50 mg/kg bodyweight

#### Routine treatment of adult dogs and cats

Administer 100 mg fenbendazole per kg bodyweight as a single dose.

Each sachet treats a 2 kg dog or cat at this dose. Treatment should be repeated 2 to 4 times per year as natural reinfection with worms occurs. More frequent treatment at 6 to 8 weekly intervals is advisable for dogs in kennels.

#### **Pregnant bitches**

Administer 25 mg fenbendazole per kg bodyweight daily from day 40 to 2 days post whelping.

Each sachet treats an 8 kg dog at this dose.

#### Weaned puppies and kittens under 6 months of age

Administer 50 mg fenbendazole per kg bodyweight daily for 3 consecutive days.

Each sachet treats a 4 kg puppy or kitten at this dose.

Smaller or unweaned puppies and kittens should be treated with Panacur 2.5% or 10% Liquid or Panacur Paste.

Puppies should be treated at 2 weeks of age, 5 weeks of age and again before leaving the breeder's premises.

Treatment may also be required at 8 and 12 weeks of age. Thereafter, frequency can be reduced unless the pups are housed in kennels where reinfection occurs more readily.

#### Increased dosing for specific infections

- For the treatment of clinical worm infestations in adult dogs and cats administer 50 mg fenbendazole per kg bodyweight daily for 3 consecutive days.
- For the control of lungworm *Oslerus (Filaroides) osleri* in dogs: 50 mg fenbendazole per kg bodyweight daily for 7 consecutive days.

A repeat course of treatment may sometimes be required.

- For the control of lungworm *Aelurostrongylus abstrusus* in cats: 50 mg fenbendazole per kg bodyweight daily for 3 consecutive days.
- For the control of protozoa *Giardia* spp. infection in dogs and puppies: 50 mg fenbendazole per kg bodyweight daily for 3 consecutive days.

#### 8. WITHDRAWAL PERIOD(S)

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

#### Contraindications, warnings etc

Assess bodyweight as accurately as possible before calculating dosage.

Direct contact with the skin should be kept to a minimum.

Wash hands after use. Avoid inhalation of granule dust.

Panacur Granules are odourless and tasteless and are readily consumed by animals.

Gastrointestinal signs (such as vomiting and diarrhoea) can occur in very rare cases in dogs and cats.

The product can also be safely administered to pregnant dogs and cats. As teratogenic effects in dogs and cats cannot be completely ruled out in very rare cases, the treatment in the first two trimesters of pregnancy should be based on the benefit-risk evaluation by the responsible veterinary surgeon.

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

#### 10. FXPIRY DATE

Exp end of: {month/year}

#### 11. SPECIAL STORAGE CONDITIONS

Keep sachets in outer carton.

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

Dispose of empty packaging and any remaining product in the household refuse.

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

#### [Distribution category]

For animal treatment only.

**NFA-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 Buckinghamshire MK7 7AJ

#### **Distributor in Northern Ireland**

Intervet Ireland Ltd.
Magna Drive
Magna Business Park
Citywest Road, Dublin 24

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

Vm 01708/4427

#### 17. MANUFACTURER'S BATCH NUMBER

Batch {number}

## PARTICULARS TO APPEAR ON THE OUTER PACKAGE {CARTON BOX/10 x 3 x 1.8 g} 1. NAME OF THE VETERINARY MEDICINAL PRODUCT Panacur Granules 222 mg/g. 2. STATEMENT OF ACTIVE SUBSTANCES 10 x 3 x 1.8 g sachets each containing 222.22 mg/g fenbendazole. 3. PHARMACEUTICAL FORM Granules 4. PACKAGE SIZE 10 x 3 x 1.8 g handy packs. **5. TARGET SPECIES** Cats, dogs, kittens and puppies. 6. INDICATION(S) Wormer for cats, dogs, kittens and puppies. 7. METHOD AND ROUTE(S) OF ADMINISTRATION Mixes into feed. 8. WITHDRAWAL PERIOD 9. SPECIAL WARNING(S), IF NECESSARY

#### 10. EXPIRY DATE

Expiry end of: {month/year}

#### 11. SPECIAL STORAGE CONDITIONS

Keep sachets in outer carton.

- 12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY
- 13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE

#### [Distribution category]

For animal treatment only.

NFA-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

#### **Distributor in Northern Ireland**

Intervet Ireland Ltd.
Magna Drive
Magna Business Park
Citywest Road, Dublin 24

#### **16. MARKETING AUTHORISATION NUMBER**

Vm 01708/4427

#### 17. MANUFACTURER'S BATCH NUMBER

Batch {number}

## PARTICULARS TO APPEAR ON THE OUTER PACKAGE {CARTON BOX/ 3 x 1.8 g}

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

Panacur Granules 222 mg/g.

#### 2. STATEMENT OF ACTIVE SUBSTANCES

3 x 1.8 g sachets each containing 222.22 mg/g fenbendazole

#### 3. PHARMACEUTICAL FORM

#### Granules

#### 4. PACKAGE SIZE

3 x 1.8 g sachets

#### **5. TARGET SPECIES**

Cats, dogs, kittens and puppies.

#### 6. INDICATION(S)

Wormer for cats, dogs, kittens and puppies.

• For the treatment of adult dogs and cats infected with roundworms and tapeworms including *Toxocara canis*, *Toxocara cati*, *Toxascaris leonina*, *Ancylostoma* spp., *Trichuris* spp., *Uncinaria* spp., and *Taenia* spp.

This pack contains sufficient Panacur Granules to treat an animal of 12 kg (26 lb) bodyweight on a single occasion. Heavier dogs will require additional packs.

• For the treatment of weaned puppies and kittens infected with gastrointestinal roundworms and puppies with protozoa *Giardia* spp.

This pack contains sufficient Panacur Granules to treat a puppy or kitten less than 6 months of age of up to 8 kg (18 lb) bodyweight for 3 consecutive days.

• For advice on the treatment of pregnant bitches and control of lungworm and protozoa *Giardia* spp. infections in cats and dogs: please consult your veterinary surgeon.

| 7. METHOD AND ROUTE(S) OF ADMINISTRATION  |
|---|
| Mixes into feed.  |
| 8. WITHDRAWAL PERIOD  |
|   |
| 9. SPECIAL WARNING(S), IF NECESSARY   |
| For uses, dosage, administration, contraindications and warnings and further information: see package leaflet.  |
| 10. EXPIRY DATE   |
| Expiry end of: {month/year}   |
| 11. SPECIAL STORAGE CONDITIONS  |
| Keep sachets in outer carton.   |
| 12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY                         |
|   |
| For uses, dosage, administration, contra-indications and warnings and further information: 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.  |

NFA-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 Buckinghamshire MK7 7AJ

#### **Distributor in Northern Ireland**

Intervet Ireland Ltd.
Magna Drive
Magna Business Park
Citywest Road, Dublin 24

#### **16. MARKETING AUTHORISATION NUMBER**

Vm 01708/4427

#### 17. MANUFACTURER'S BATCH NUMBER

Batch {number}

#### PARTICULARS TO APPEAR ON THE OUTER PACKAGE

{Carton box/ 90 x 1.8 g}

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

Panacur Granules 222 mg/g

#### 2. STATEMENT OF ACTIVE SUBSTANCES

90 x 1.8 g sachets each containing 222.22 mg/g fenbendazole

#### 3. PHARMACEUTICAL FORM

A white granulate formulation of fenbendazole as a ready to use oral anthelmintic.

#### 4. PACKAGE SIZE

90 x 1.8 g sachets

#### 5. TARGET SPECIES

Cats, dogs, kittens and puppies.

#### 6. INDICATION(S)

Wormer for cats, dogs, kittens and puppies.

- For the treatment of adult dogs and cats infected with gastrointestinal roundworms and tapeworms including *Toxocara canis*, *Toxocara cati*, *Toxascaris leonina*, *Ancylostoma* spp., *Trichuris* spp., *Uncinaria* spp., and *Taenia* spp.
- For the treatment of weaned puppies and kittens infected with gastrointestinal roundworms.
- For the treatment of pregnant bitches, to reduce pre-natal infection with *Toxocara canis* and the transfer of *T. canis* and *Ancylostoma caninum* to the pups via milk.
- For the treatment of adult dogs and puppies with protozoa *Giardia* spp.
- Also effective against lungworms *Oslerus (Filaroides) osleri* in dogs and *Aelurostrongylus abstrusus* in cats.

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

Mixes into feed

4 kg dose at 100 mg/kg bodyweight

8 kg dose at 50 mg/kg bodyweight

#### Routine treatment of adult dogs and cats

Administer 100 mg fenbendazole per kg bodyweight as a single dose.

Each sachet treats a 4 kg dog or cat at this dose. Treatment should be repeated 2 to 4 times per year as natural reinfection with worms occurs. More frequent treatment at 6 to 8 weekly intervals is advisable for dogs in kennels.

#### **Pregnant bitches**

Administer 25 mg fenbendazole per kg bodyweight daily from day 40 to 2 days post whelping (approximately 25 days).

Each sachet treats a 16 kg dog at this dose.

#### Weaned puppies and kittens under 6 months of age

Administer 50 mg fenbendazole per kg bodyweight daily for 3 consecutive days.

Each sachet treats an 8 kg puppy or kitten at this dose.

Smaller or unweaned puppies and kittens should be treated with Panacur 2.5% or 10% Liquid or Panacur Paste.

Puppies should be treated at 2 weeks of age, 5 weeks of age and again before leaving the breeder's premises.

Treatment may also be required at 8 and 12 weeks of age. Thereafter, frequency can be reduced unless the pups are housed in kennels where reinfection occurs more readily.

#### Increased dosing for specific infections

- For the treatment of clinical worm infestations in adult dogs and cats administer 50 mg fenbendazole per kg bodyweight daily for 3 consecutive days.
- For the control of lungworm *Oslerus (Filaroides) osleri* in dogs: 50 mg fenbendazole per kg bodyweight daily for 7 consecutive days.

A repeat course of treatment may sometimes be required.

• For the control of lungworm *Aelurostrongylus abstrusus* in cats: 50 mg fenbendazole per kg bodyweight daily for 3 consecutive days.

• For the control of protozoa *Giardia* spp. infection in dogs and puppies: 50 mg fenbendazole per kg bodyweight daily for 3 consecutive days.

#### 8. WITHDRAWAL PERIOD

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

#### Contraindications, warnings, etc.

Gastrointestinal signs (such as vomiting and diarrhoea) can occur in very rare cases in dogs and cats.

The product can also be safely administered to pregnant dogs and cats. As teratogenic effects in dogs and cats cannot be completely ruled out in very rare cases, the treatment in the first two trimesters of pregnancy should be based on the benefit-risk evaluation by the responsible veterinary surgeon.

Assess bodyweight as accurately as possible before calculating dosage.

Direct contact with the skin should be kept to a minimum.

Wash hands after use. Avoid inhalation of granule dust.

Panacur Granules are odourless and tasteless and are readily consumed by animals.

#### 10. EXPIRY DATE

Exp end of: {month/year}

#### 11. SPECIAL STORAGE CONDITIONS

Keep sachets in outer carton.

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

Dispose of empty packaging and any remaining product in the household refuse.

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

#### [Distribution category]

For animal treatment only.

NFA-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 Buckinghamshire MK7 7AJ

#### Distributor in Northern Ireland

Intervet Ireland Ltd. Magna Drive Magna Business Park Citywest Road, Dublin 24

#### **16. MARKETING AUTHORISATION NUMBER**

Vm 01708/4427

#### 17. MANUFACTURER'S BATCH NUMBER

Batch {number}

## PARTICULARS TO APPEAR ON THE OUTER PACKAGE {CARTON BOX/10 x 3 x 4.5 g } 1. NAME OF THE VETERINARY MEDICINAL PRODUCT Panacur Granules 222 mg/g. 2. STATEMENT OF ACTIVE SUBSTANCES 10 x 3 x 4.5 g sachets each containing 222.22 mg/g fenbendazole. 3. PHARMACEUTICAL FORM Granules 4. PACKAGE SIZE 10 x 3 x 4.5 g handy packs. **5. TARGET SPECIES** Cats, dogs, kittens and puppies. 6. INDICATION(S) Wormer for cats, dogs, kittens and puppies 7. METHOD AND ROUTE(S) OF ADMINISTRATION Mixes into feed. 8. WITHDRAWAL PERIOD

9. SPECIAL WARNING(S), IF NECESSARY

#### 10. EXPIRY DATE

Expiry end of: {month/year}

#### 11. SPECIAL STORAGE CONDITIONS

Keep sachets in outer carton.

- 12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY
- 13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE

#### [Distribution category]

For animal treatment only.

NFA-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 Buckinghamshire MK7 7AJ

#### **Distributor in Northern Ireland**

Intervet Ireland Ltd.
Magna Drive
Magna Business Park
Citywest Road, Dublin 24

#### **16. MARKETING AUTHORISATION NUMBER**

Vm 01708/4427

#### 17. MANUFACTURER'S BATCH NUMBER

Batch: {number}

## PARTICULARS TO APPEAR ON THE OUTER PACKAGE {CARTON BOX/ 3 x 4.5 g}

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

Panacur Granules 222 mg/g.

#### 2. STATEMENT OF ACTIVE SUBSTANCES

3 x 4.5 g sachets each containing 222.22 mg/g fenbendazole

#### 3. PHARMACEUTICAL FORM

#### Granules

#### 4. PACKAGE SIZE

3 x 4.5 g sachets

#### **5. TARGET SPECIES**

Cats, dogs, kittens and puppies.

#### 6. INDICATION(S)

Wormer for cats, dogs, kittens and puppies.

• For the treatment of adult dogs and cats infected with roundworms and tapeworms including *Toxocara canis*, *Toxocara cati*, *Toxascaris leonina*, Ancylostoma spp., Trichuris spp., Uncinaria spp., and Taenia spp.

This pack contains sufficient Panacur Granules to treat an animal of 30 kg (66 lb) bodyweight on a single occasion. Heavier dogs will require additional packs.

• For the treatment of weaned puppies and kittens infected with gastrointestinal roundworms and puppies with protozoa *Giardia* spp.

This pack contains sufficient Panacur Granules to treat a puppy or kitten less than 6 months of age of up to 20 kg (44 lb) bodyweight for 3 consecutive days.

• For advice on the treatment of pregnant bitches and control of lungworm and protozoa *Giardia* spp. infections in cats and dogs: please consult your veterinary surgeon.

| AN. 01230/2022 & 01230/202  |
|---|
| 7. METHOD AND ROUTE(S) OF ADMINISTRATION  |
| Mixes into feed.  |
| 8. WITHDRAWAL PERIOD  |
|   |
| 9. SPECIAL WARNING(S), IF NECESSARY   |
| For uses, dosage, administration, contraindications and warnings and further information: see package leaflet.  |
| 10. EXPIRY DATE   |
| Expiry end of: {month/year}   |
| 11. SPECIAL STORAGE CONDITIONS  |
| Keep sachets in outer carton.   |
| 12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY                         |
| For uses, dosage, administration, contraindications and warnings and further information: 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.  |

NFA-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 Buckinghamshire MK7 7AJ

#### **Distributor in Northern Ireland**

Intervet Ireland Ltd.
Magna Drive
Magna Business Park
Citywest Road, Dublin 24

#### 16. MARKETING AUTHORISATION NUMBER

Vm 01708/4427

#### 17. MANUFACTURER'S BATCH NUMBER

Batch {number}

#### PARTICULARS TO APPEAR ON THE OUTER PACKAGE

{CARTON BOX/60 x 4.5 g}

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

Panacur Granules 222 mg/g.

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

60 x 4.5 g sachets each containing 222.22 mg/g fenbendazole

#### 3. PHARMACEUTICAL FORM

A white granulate formulation of fenbendazole as a ready to use oral anthelmintic.

#### 4. PACKAGE SIZE

60 x 4.5 g sachets

#### **5. TARGET SPECIES**

Cats, dogs, kittens and puppies.

#### 6. INDICATION(S)

Wormer for cats, dogs, kittens and puppies.

- For the treatment of adult dogs and cats infected with gastro-intestinal roundworms and tapeworms including *Toxocara canis*, *Toxocara cati*, *Toxascaris leonina*, *Ancylostoma* spp., *Trichuris* spp., *Uncinaria* spp., and *Taenia* spp.
- For the treatment of weaned puppies and kittens infected with gastrointestinal roundworms.
- For the treatment of pregnant bitches, to reduce pre-natal infection with *Toxocara* canis and the transfer of *T. canis* and *Ancylostoma caninum* to the pups via milk.
- For the treatment of adult dogs and puppies with protozoa Giardia spp.
- Also effective against lungworms *Oslerus (Filaroides) osleri* in dogs and *Aelurostrongylus abstrusus* in cats.

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

Mixes into feed

10 kg dose at 100 mg/kg bodyweight

20 kg dose at 50 mg/kg bodyweight

#### Routine treatment of adult dogs and cats

Administer 100 mg fenbendazole per kg bodyweight as a single dose.

Each sachet treats a 10 kg dog or cat at this dose. Treatment should be repeated 2 to 4 times per year as natural reinfection with worms occurs. More frequent treatment at 6 to 8 weekly intervals is advisable for dogs in kennels.

#### **Pregnant bitches**

Administer 25 mg fenbendazole per kg bodyweight daily from day 40 to 2 days post whelping.

Each sachet treats a 40 kg dog at this dose.

#### Weaned puppies and kittens under 6 months of age

Administer 50 mg fenbendazole per kg bodyweight daily for 3 consecutive days.

Each sachet treats a 20 kg puppy or kitten at this dose.

Smaller or unweaned puppies and kittens should be treated with Panacur 2.5% or 10% Liquid or Panacur Paste.

Puppies should be treated at 2 weeks of age, 5 weeks of age and again before leaving the breeder's premises.

Treatment may also be required at 8 and 12 weeks of age. Thereafter, frequency can be reduced unless the pups are housed in kennels where reinfection occurs more readily.

#### Increased dosing for specific infections

- For the treatment of clinical worm infestations in adult dogs and cats administer 50 mg fenbendazole per kg bodyweight daily for 3 consecutive days.
- For the control of lungworm *Oslerus (Filaroides) osleri* in dogs: 50 mg fenbendazole per kg bodyweight daily for 7 consecutive days.

A repeat course of treatment may sometimes be required.

- For the control of lungworm *Aelurostrongylus abstrusus* in cats: 50 mg fenbendazole per kg bodyweight daily for 3 consecutive days.
- For the control of protozoa *Giardia* spp. infection in dogs and puppies: 50 mg fenbendazole per kg bodyweight daily for 3 consecutive days.

#### 8. WITHDRAWAL PERIOD

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

#### Contra-indications, warnings etc

Assess bodyweight as accurately as possible before calculating dosage.

Direct contact with the skin should be kept to a minimum.

Wash hands after use. Avoid inhalation of granule dust.

Gastrointestinal signs (such as vomiting and diarrhoea) can occur in very rare cases in dogs and cats.

The product can also be safely administered to pregnant dogs and cats. As teratogenic effects in dogs and cats cannot be completely ruled out in very rare cases, the treatment in the first two trimesters of pregnancy should be based on the benefit-risk evaluation by the responsible veterinary surgeon.

Panacur Granules are odourless and tasteless and are readily consumed by animals.

#### 10. EXPIRY DATE

Exp end of: {month/year}

#### 11. SPECIAL STORAGE CONDITIONS

Keep sachets in outer carton.

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

Dispose of empty packaging and any remaining product in the household refuse.

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

#### [Distribution category]

For animal treatment only.

NFA-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 Buckinghamshire MK7 7AJ

#### **Distributor in Northern Ireland**

Intervet Ireland Ltd.
Magna Drive
Magna Business Park
Citywest Road, Dublin 24

#### 16. MARKETING AUTHORISATION NUMBER

Vm 01708/4427

#### 17. MANUFACTURER'S BATCH NUMBER

Batch {number}

## PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE {LABEL [SACHETS]/1 g, 1.8 g, 4.5 g}

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

Panacur Granules 222 mg/g.

#### 2. STATEMENT OFACTIVE SUBSTANCES

Panacur Granules sachets contain 222.22 mg/g fenbendazole.

#### 3. PHARMACEUTICAL FORM

Granules

#### 4. PACKAGE SIZE

1 g

1.8 g

4.5 g

#### 5. TARGET SPECIES

Cats, dogs, kittens and puppies.

#### 6. INDICATION(S)

Wormer for cats, dogs, kittens and puppies.

- For the treatment of adult dogs and cats infected with roundworms and tapeworms including *Toxocara canis*, *Toxocara cati*, *Toxascaris leonina*, *Ancylostoma* spp., *Trichuris* spp., *Uncinaria* spp., and *Taenia* spp. Also effective against lungworms *Oslerus* (*Filaroides*) *osleri* and *Aelurostrongylus abstrusus* in cats.
- For the treatment of weaned puppies and kittens infected with gastrointestinal roundworms. For the treatment of puppies infected with protozoa *Giardia* spp.
- For the treatment of pregnant bitches, to reduce pre-natal infection with *Toxocara* canis and the transfer of *T. canis* and *Ancylostoma caninum* to the pups via the milk.

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

#### Mixes into feed

#### **Dosage: this 1g sachet treats:**

- **Routine treatment** of adult dogs and cats: 1 sachet Panacur Granules per 2 kg (4.5 lb) bodyweight on a single occasion.
- Weaned puppies and kittens under 6 months of age and lungworm in cats: 1 sachet per 4 kg (9 lb) bodyweight daily for 3 days.
- **Pregnant bitches:** 1 sachet per 8 kg (18 lb) daily from day 40 of pregnancy to 2 days post-whelping (approx. 25 days).
- Lungworm in dogs: 1 sachet per 4 kg (9 lb) bodyweight daily for 7 days. A repeat treatment may be necessary.
- Protozoa Giardia spp. infections in dogs and puppies: 1 sachet per 4 kg (9 lb) bodyweight daily for 3 days.

#### Dosage: this 1.8 g sachet treats:

- Routine treatment of adult dogs and cats: 1 sachet Panacur Granules per 4 kg (9 lb) bodyweight on a single occasion.
- Weaned puppies and kittens under 6 months of age and lungworm in cats: 1 sachet per 8 kg (18 lb) bodyweight daily for 3 days.
- **Pregnant bitches:** 1 sachet per 16 kg (36 lb) daily from day 40 of pregnancy to 2 days post-whelping (approx. 25 days).
- Lungworm in dogs: 1 sachet per 8 kg bodyweight daily for 7 days. A repeat treatment may be necessary.
- Protozoa Giardia spp. infections in dogs and puppies: 1 sachet per 8 kg (18 lb) bodyweight daily for 3 days.

#### Dosage: this 4.5 g sachet treats:

- Routine treatment of adult dogs and cats: 1 sachet Panacur Granules per 10 kg (22 lb) bodyweight on a single occasion.
- Weaned puppies and kittens under 6 months of age and lungworm in cats: 1 sachet per 20 kg (44 lb) bodyweight daily for 3 days.
- **Pregnant bitches:** 1 sachet per 40 kg (88 lb) daily from day 40 of pregnancy to 2 days post-whelping (approx. 25 days).
- Lungworm in dogs: 1 sachet per 20 kg (44 lb) bodyweight daily for 7 days. A repeat treatment may be necessary.
- Protozoa Giardia spp. infections in dogs and puppies: 1 sachet per 20 kg (44 lb) bodyweight daily for 3 days.

Panacur Granules are odourless and tasteless and are readily consumed by animals.

Treatment should be repeated when natural reinfestation of animals with parasitic worms occurs.

Treatment of adult dogs and cats is advisable 2 to 4 times a year.

Puppies should be treated at 2 weeks of age and again at 5 weeks of age. Further treatments are recommended at 8 and 12 weeks of age. Thereafter, frequency can be reduced unless the pups are housed in kennels where reinfection occurs more readily.

#### 8. WITHDRAWAL PERIOD(S)

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

Direct contact with the skin should be kept to a minimum.

Wash hands after use. Avoid inhalation of granule dust.

Assess bodyweight as accurately as possible before calculating dosage.

**Adverse reactions:** Gastrointestinal signs (such as vomiting and diarrhoea) can occur in very rare cases in dogs and cats.

**Use during pregnancy or lactation:** The product can also be safely administered to pregnant dogs and cats. As teratogenic effects in dogs and cats cannot be completely ruled out in very rare cases, the treatment in the first two trimesters of pregnancy should be based on the benefit-risk evaluation by the responsible veterinary surgeon.

#### **10. EXPIRY DATE**

EXP end of: {month/year}

#### 11. SPECIAL STORAGE CONDITIONS

Keep sachet in outer carton

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

Dispose of empty packaging and any remaining product in the household refuse.

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

| For anima | l treatm | ent only |
|-----------|----------|----------|
|-----------|----------|----------|

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#### 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 Buckinghamshire MK7 7AJ

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

Vm 01708/4427

#### 17. MANUFACTURER'S BATCH NUMBER

Batch {number}

#### PACKAGE LEAFLET FOR (10 x 3 x 1.8 g pack):

#### Panacur Granules 222 mg/g

# 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, UK

Manufacturer responsible for batch release:

Intervet GesmbH Siemensstrasse 107 1210 Vienna Austria

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

Panacur Granules 222 mg/g

Fenbendazole

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

Each 1.8 g sachet of white odourless and tasteless granules contains 222.22 mg/g fenbendazole

#### 4. INDICATION(S)

For the treatment of adult dogs and cats infected with gastrointestinal roundworms and tapeworms including *Toxocara canis*, *Toxocara cati*, *Toxascaris leonina*, *Ancylostoma* spp., *Trichuris* spp., *Uncinaria* spp., and *Taenia* spp.

For the treatment of weaned puppies and kittens infected with gastrointestinal roundworms and puppies infected with protozoa *Giardia* spp.

#### 5. CONTRAINDICATIONS

None.

#### 6. ADVERSE REACTIONS

Gastrointestinal signs (such as vomiting and diarrhoea) can occur in very rare cases in dogs and cats.

The frequency of adverse reactions is defined using the following convention:

- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

#### 7. TARGET SPECIES

Dogs, cats, puppies and kittens.

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

Panacur Granules should be mixed into the feed.

#### Routine treament of adult dogs and cats

Each 1.8 gm sachet will dose up to 4 kg (9 lbs) adult bodyweight.

Administer 1 sachet per 4 kg (9 lbs) as single dose.

Weight of animal

2-4 kg (4-9 lbs)

3-4 kg (9.1-18 lbs)

4.1-8 kg (9.1-18 lbs)

5-4 kg (9.1-18 lbs)

7-5 Two 1.8 g sachets

7-6 Three 1.8 g sachets

For dogs weighing over 12 kg (26 lbs) an extra 1.8 g sachet is required for each 4 kg (9 lbs) of bodyweight.

Panacur Granules are also available in 3 x 4.5 g sachet handy packs.

Treatment should be repeated when natural reinfestation with parasitic worms occurs.

Routine treatment of adult animals with minimal exposure to infection is advisable 2 to 4 times per year.

More frequent treatment at 6 to 8 weekly intervals is recommended for dogs in kennels where reinfection occurs more readily.

#### Weaned puppies and kittens under 6 months of age

Each 1.8 g sachet will dose up to 8 kg (18 lbs) bodyweight.

Administer 1 sachet per 8 kg (18 lbs) daily for 3 consecutive days.

Smaller or unweaned puppies or kittens should be treated with Panacur 2.5% or 10% Liquid or Panacur Paste.

Puppies should be treated at 2 weeks of age, 5 weeks of age and again before leaving the breeder's premises.

Treatment may also be required at 8 and 12 weeks of age.

Thereafter, frequency of treatment can be reduced unless the pups remain in kennels where reinfection occurs more readily.

• For advice on the treatment of pregnant bitches and control of lungworms or protozoa *Giardia* spp. in cats and dogs - please consult your veterinary surgeon.

#### 9. ADVICE ON CORRECT ADMINISTRATION

Panacur Granules are odourless and tasteless and are readily consumed by animals. Fussy cats should receive the granules in their favourite food.

#### 10. WITHDRAWAL PERIOD(S)

Not applicable.

#### 11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

Keep sachets in outer carton.

This veterinary medicinal product does not require special storage conditions.

#### 12. SPECIAL WARNING(S)

#### Special warnings for each target species:

The use of this product should be based on local epidemiological information about susceptibility of the nematodes and recommendations on how to limit further selection for resistance to anthelmintics.

#### Special precautions for use in animals:

Assess bodyweight as accurately as possible before calculating dosage.

### 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. Wash hands after use. Avoid inhalation of granule dust.

#### Pregnancy:

The product can also be safely administered to pregnant dogs and cats. As teratogenic effects in dogs and cats cannot be completely ruled out in very rare cases, the treatment in the first two trimesters of pregnancy should be based on the benefit-risk evaluation by the responsible veterinary surgeon.

#### 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

Dispose of empty packaging and any remaining product in the household refuse.

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

March 2023

#### 15. OTHER INFORMATION

For animal treatment only.

Pack sizes: 3 x 1.8 g sachets.

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Vm 01708/4427

#### **Distributor in Northern Ireland**

Intervet Ireland Ltd.
Magna Drive,
Magna Business Park,
Citywest Road,
Dublin 24

#### PACKAGE LEAFLET FOR (10 x 3 x 4.5 g pack): Panacur Granules 222 mg/g

# 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 GesmbH Siemensstrasse 107 1210 Vienna Austria

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

Panacur Granules 222 mg/g

Fenbendazole

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

Each 4.5 g sachet of white odourless and tasteless granules contains 222.2 mg/g fenbendazole.

#### 4. INDICATION(S)

For the treatment of adult dogs and cats infected with gastrointestinal roundworms and tapeworms including *Toxocara canis*, *Toxocara cati*, *Toxascaris leonina*, *Ancylostoma* spp., Trichuris spp., *Uncinaria* spp., and *Taenia* spp. For the treatment of weaned puppies and kittens infected with gastrointestinal roundworms and puppies infected with protozoa *Giardia spp*.

#### 5. CONTRAINDICATIONS

None

#### 6. ADVERSE REACTIONS

Gastrointestinal signs (such as vomiting and diarrhoea) can occur in very rare cases in dogs and cats.

The frequency of adverse reactions is defined using the following convention:

- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

#### 7. TARGET SPECIES

Dogs, cats, puppies and kittens.

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

Panacur Granules should be mixed into the feed.

#### Routine treament of adult dogs and cats

Each 4.5 gm sachet will dose up to 10 kg (22 lbs) adult bodyweight.

Administer 1 sachet per 10 kg (22 lbs) as single dose.

 Weight of animal
 Single dose required

 5-10 kg (11-22 lbs)
 One 4.5 g sachet

 10.1-20 kg (22.2-44 lbs)
 Two 4.5 g sachets

 20.1-30 kg (44.2- 66 lbs)
 Three 4.5 g sachets

For dogs weighing over 30 kg (66 lbs) an extra 4.5 g sachet is required for each 10 kg (22 lbs) of bodyweight.

Panacur Granules are also available in 3 x 1.8 g sachet handy packs.

Treatment should be repeated when natural reinfestation with parasitic worms occurs.

Routine treatment of adult animals with minimal exposure to infection is advisable 2 to 4 times per year.

More frequent treatment at 6 to 8 weekly intervals is recommended for dogs in kennels where reinfection occurs more readily.

#### Weaned puppies and kittens under 6 months of age

Each 4.5 g sachet will dose up to 20 kg (44 lbs) bodyweight.

Administer 1 sachet per 20 kg (44 lbs) daily for 3 consecutive days.

Smaller or unweaned puppies or kittens should be treated with Panacur 2.5% or 10% Liquid or Panacur Paste.

Puppies should be treated at 2 weeks of age, 5 weeks of age and again before leaving the breeder's premises.

Treatment may also be required at 8 and 12 weeks of age.

Thereafter, frequency of treatment can be reduced unless the pups remain in kennels where reinfection occurs more readily.

• For advice on the treatment of pregnant bitches and control of lungworms or protozoa *Giardia* spp. in cats and dogs - please consult your veterinary surgeon.

#### 9. ADVICE ON CORRECT ADMINISTRATION

Panacur Granules are odourless and tasteless and are readily consumed by animals. Fussy cats should receive the granules in their favourite food.

#### 10. WITHDRAWAL PERIOD(S)

Not applicable.

#### 11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

Keep sachets in outer carton.

This veterinary medicinal product does not require special storage conditions.

#### 12. SPECIAL WARNING(S)

#### Special warnings for each target species:

The use of this product should be based on local epidemiological information about susceptibility of the nematodes and recommendations on how to limit further selection for resistance to anthelmintics.

#### Special precautions for use in animals:

Assess bodyweight as accurately as possible before calculating dosage.

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. Wash hands after use. Avoid inhalation of granule dust.

#### Pregnancy:

The product can also be safely administered to pregnant dogs and cats. As teratogenic effects in dogs and cats cannot be completely ruled out in very rare cases, the treatment in the first two trimesters of pregnancy should be based on the benefit-risk evaluation by the responsible veterinary surgeon.

#### 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

Dispose of empty packaging and any remaining product in the household refuse.

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

March 2023

#### 15. OTHER INFORMATION

For animal treatment only.

Pack sizes: 3 x 4.5 g sachets

NFA-VPS Vm 01708/4427

#### **Distributor in Northern Ireland**

Intervet Ireland Ltd.
Magna Drive,
Magna Business Park,
Citywest Road,
Dublin 24

Approved 08 March 2023

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