PARTICULARS TO APPEAR ON THE OUTER PACKAGE – CARDBOARD CARTON AND PACKAGE LEAFLET

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Granofen Wormer 444.4mg Granules for Dogs and Cats

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Fenbendazole 444.4mg

3. PHARMACEUTICAL FORM

Granules for oral administration

4. PACKAGE SIZE

Box of 120 x 2g sachets

5. TARGET SPECIES

Dogs and cats

6. INDICATION(S)

Granofen Wormer 444.4mg Granules for Dogs and Cats is a broad spectrum anthelmintic for the treatment of domestic dogs and cats infected with immature and mature stages of nematodes of the gastro-intestinal and respiratory tracts. Granofen Wormer 444.4mg Granules for Dogs and Cats also has an ovicidal effect on nematode eggs.

Adult dogs and cats: For the treatment of adult dogs and cats infected with gastrointestinal nematodes and cestodes: *Ascarid* spp, *Ancylostoma* spp, *Uncinaria* spp, *Trichuris* spp, and *Taenia* spp.

Puppies and kittens: For the treatment of weaned puppies and kittens infected with gastro-intestinal nematodes.

Pregnant bitches: For the treatment of pregnant bitches to reduce pre-natal infections with *Toxocara canis* and the transfer of *Toxocara canis* and *Ancylostoma caninum* to their pups *via* the milk.

Also for the treatment of lungworm nematodes of domestic dogs affected with *Oslerus (Filaroides) osleri*, and domestic cats affected with *Aelurostrongylus abstrusus*.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Routine treatment of adult dogs and cats: administer a sachet of 2g Granofen Wormer 444.4mg Granules for Dogs and Cats per 8.8kg (20 lbs) bodyweight as a single dose (equivalent to 100mg fenbendazole/kg bodyweight)

Practical Dosage Recommendations:

2.2 to 4.4 kg (5-10 lbs) 2 grams

4.4 to 8.8 kg (10-20 lbs) 4 grams

8.8 to 13.2 kg (20-30 lbs) 6 grams

13.3 to 22 kg (30-50 lbs) 10 grams

22.1 to 35.2 kg (50-80 lbs) 16 grams

35.3 to 50 kg (80-110 lbs) 22 grams

For dogs weighing over 50 kg (110 lbs), an extra 1g is required for each additional 2.2 kg of bodyweight.

The dose should be administered by mixing into the feed. Treatment should be repeated when natural reinfection 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 advisable for dogs in kennels.

Increased dosing for specific infections:

For the control of lungworm *Oslerus (Filaroides) osleri* in dogs administer a sachet of 2g Granofen Wormer 444.4mg Granules for Dogs and Cats per 8.8 kg (20 lbs) bodyweight daily for 7 consecutive days, (= 50 mg fenbendazole/kg bodyweight daily for 7 days). A repeat course of treatment may be required in some cases.

For the treatment of clinical worm infestations in adult dogs and cats administer a sachet of 2g Granofen Wormer 444.4mg Granules for Dogs and Cats per 8.8 kg (20 lbs) bodyweight daily for 3 consecutive days, (=50 mg fenbendazole/kg bodyweight daily for 3 days).

Pregnant bitches:

Administer a sachet of 2g Granofen Wormer 444.4mg Granules for Dogs and Cats per 17.6 kg (40 lbs) bodyweight daily from day 40 of pregnancy continuously to 2 days post weaning (approximately 25 days) (= 25 mg fenbendazole/kg bodyweight daily).

Practical dosage recommendations:

Bodyweight	Daily dose for approx. 25 days

8.8 kg (20 lbs)	1 gram
17.6 kg (40 lbs)	2 grams
26.4 kg (60 lbs)	3 grams
35.2 kg (80 lbs)	4 grams
45 kg (100 lbs)	5 grams

For bitches weighing over 45 kg, an extra 1g is required daily for each additional 8.8 kg (20lbs) bodyweight.

Weaned puppies and kittens under six months of age:

Administer a sachet of 2g Granofen Wormer 444.4mg Granules for Dogs and Cats per 8.8 kg (20 lbs) bodyweight daily for 3 consecutive days mixed into the feed (= 50 mg fenbendazole/kg bodyweight daily for 3 days)

For dogs/puppies weighing over 22 kg (50 lbs), an extra 1 gram is required daily for each additional 4.4 kg (10 lbs) bodyweight. 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 remain in kennels where reinfestation occurs more readily.

Practical dosage recommendations:

Bodyweight	Daily dose for 3 days
2.2 to 4.4 kg (5-10 lbs)	1 gram
4.4 to 8.8 kg (10-20 lbs)	2 grams
8.8 to 13.2 kg (20-30 lbs)	3 grams
13.2 to 22 kg (30-50 lbs)	5 grams

8. WITHDRAWAL PERIOD

N/A

9. SPECIAL WARNING(S), IF NECESSARY

Operator warnings: Direct contact with the skin should be kept to a minimum. Avoid inhalation of dust. Wash hands after use.

For animal treatment only.

Keep out of the reach and sight of children

Assess bodyweight as accurately as possible before calculating the dosage. Keep sachet in outer carton. Add to feed immediately before administration. Discard any remaining medicated feed.

10. EXPIRY DATE

11. SPECIAL STORAGE CONDITIONS

Store in a dry place.

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

Environmental warnings: Dispose of used containers and sachets safely. Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

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

NFA-VPS

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

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Virbac Limited, Woolpit Business Park,Windmill Avenue, Woolpit

Bury St Edmunds, Suffolk IP30 9UP

16. MARKETING AUTHORISATION NUMBER(S)

Vm 11188/4010

17. MANUFACTURER'S BATCH NUMBER

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS - Sachets consisting of paper, low density polyethylene and foil containing 2g of granules, with a heat-seal closure.

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Granofen Wormer 444.4mg Granules for Dogs and Cats

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Fenbendazole 444.4mg

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

2g sachets

4. ROUTE(S) OF ADMINISTRATION

Oral

5. WITHDRAWAL PERIOD

N/A

6. BATCH NUMBER

7. EXPIRY DATE

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

PACKAGE LEAFLET FOR: Granofen Wormer 444.4mg Granules for Dogs and Cats

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

Virbac Limited, Woolpit Business Park,Windmill Avenue, Woolpit

Bury St Edmunds, Suffolk IP30 9UP

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Granofen Wormer 444.4mg Granules for Dogs and Cats

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

Fenbendazole 444.4mg

Lactose monohydrate

Povidone K30

Sodium Lauryl Sulphate

4. INDICATION(S)

Granofen Wormer 444.4mg Granules for Dogs and Cats is indicated for the treatment of immature and mature stages of nematodes of the gastro-intestinal and respiratory tracts of domestic dogs and cats. It also has an ovicidal effect and is indicated for the following:

For the treatment of gastrointestinal nematodes and cestodes of domestic dogs and cats affected with *Ascarid* spp., *Ancylostoma* spp., *Uncinaria* spp., *Trichuris* spp., and *Taenia* spp. Also for the treatment of lungworm nematodes of domestic dogs affected with *Oslerus (Filaroides) osleri*, and domestic cats affected with *Aelurostrongylus abstrusus*.

For the treatment of pregnant bitches to reduce pre-natal infections with *Toxocara canis* and the transfer of *Toxocara canis* and *Ancylostoma caninum* to their pups *via* the milk.

5. CONTRAINDICATIONS

Known hypersensitivity to the active ingredient.

6. ADVERSE REACTIONS

None known

7. TARGET SPECIES

Dogs and cats

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

For oral administration only sprinkled onto food or by mouth.

For the routine treatment of adult dogs and cats a dosage of 100 mg/kg is recommended.

For treatment of weaned puppies and kittens 50 mg/kg daily for three days is recommended.

For the control of lungworm, *Oslerus (Filaroides) osleri*, 50 mg fenbendazole per kg per day for 7 days. A repeated course of treatment may be required in some cases.

For the control of lungworm in cats, *Aelurostrongylus abstrusus*, 20 mg fenbendazole/kg per day for five days.

For the treatment of pregnant bitches daily dosage of 25 mg fenbendazole/kg from day 40 of pregnancy continuously to 2 days post-whelping.

For the treatment of *clinical* worm infestations in adult dogs and cats administer a sachet of 2g Granofen Wormer 444.4mg Granules for Dogs and Cats per 8.8 kg (20 lbs) bodyweight daily for 3 consecutive days (=50 mg fenbendazole per kg bodyweight daily for 3 days).

Assess bodyweight as accurately as possible prior to determining the correct dosage.

9. ADVICE ON CORRECT ADMINISTRATION

See section 8 above

10. WITHDRAWAL PERIOD(S)

N/A

11. SPECIAL STORAGE PRECAUTIONS

Store in a dry place.

Add to feed immediately before administration. Discard any remaining medicated feed.

12. SPECIAL WARNING(S)

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

For Animal Treatment Only

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

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

January 2009

15. OTHER INFORMATION

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Approved: 25/07/2017