SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Granofen Wormer 222.2mg Granules for Dogs and Cats

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 1g sachet contains:

Active substance: **mg**

Fenbendazole. ……..222.2

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Granules

A free flowing white to greyish white granular powder

4. CLINICAL PARTICULARS

4.1 Target species

Dogs and Cats.

4.2 Indications for use, specifying the target species

Granofen Wormer 222.2mg 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.

4.3 Contraindications

Known hypersensitivity to the active ingredient.

4.4 Special warnings for each target species

Not applicable.

4.5 Special precautions for use

Special precautions for use in animals

None

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.

4.6 Adverse reactions (frequency and seriousness)

None known

4.7 Use during pregnancy and lactation

Granofen Wormer 222.2mg Granules for Dogs and Cats may be safely used in pregnant and young animals when administered according to the recommended dosing schedules.

4.8 Interaction with other medicinal products and other forms of interaction

None known.

4.9 Amounts to be administered and administration route

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 1g Granofen Wormer 222.2mg Granules for Dogs and Cats per 4.4 kg (10 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.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

Benzimidazoles have a wide margin of safety.

4.11 Withdrawal period(s)

Not applicable.

5. PHARMACOLOGICAL PROPERTIES

Anthelminthics (Benzimidazoles and related substances)

ATC code: QP52AC13

Contains fenbendazole which is a member of the benzimidazole family of anthelmintics and has been in veterinary use for a number of years. Fenbendazole acts against parasites by disrupting the formation of microtubules by binding to tubulin in parasitic intestinal cells hence preventing the absorption of glucose, parasites are gradually starved to death. Fenbendazole displays preference for parasitic as opposed to mammalian tubulin; this appears to be due to the fact that the formation of the parasitic tubulin-fenbendazole complex is more favourable kinetically under physiological conditions than the mammalian complex.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lactose monohydrate

Povidone K30

Sodium Lauryl Sulphate

6.2 Incompatibilities

None known.

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years.

6.4. Special precautions for storage

Store in a dry place.

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

6.5 Nature and composition of immediate packaging

Sachets consisting of paper, low density polyethylene and foil containing 1g of granules, with a heat-seal closure.

Carton containing 180 x 1 g sachets

6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

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

7. MARKETING AUTHORISATION HOLDER

Virbac Limited
Woolpit Business Park
Windmill Avenue
Woolpit
Bury St Edmunds
Suffolk IP30 9UP

8. MARKETING AUTHORISATION NUMBER(S)

VM 11188/4003

9. DATE OF FIRST AUTHORISATION

11th February 1998

10 DATE OF REVISION OF THE TEXT

February 2009