SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Bob Martin Clear Wormer Granules for Dogs 888.8mg

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 4g sachet contains:

	Active Substance(s) mg
Fenbendazole……	*888.8*

For a full list of excipients see section 6.1.

3. PHARMACEUTICAL FORM

Granules.

White to off-white, free flowing, coarse granules.

4. CLINICAL PARTICULARS

4.1 Target species

Dog

4.2 Indications for use, specifying the target species

The product is indicated for the treatment of common gastro-intestinal roundworms that can infect dogs.

The product also has an ovicidal effect on nematode eggs.

4.3 Contra-Indications

Known hypersensitivity to active substance.

4.4 Special warnings for each target species

Do not administer if your dog is sick or recovering from an illness.

4.5 Special precautions for use

i) Special precautions for use in animals

None.

ii) 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, lactation or lay

Not recommended for the treatment of pregnant bitches.
Nursing bitches should be treated at the same time as their puppies.

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.

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

Administer 4g of 'the product per 8.8kg (19lb 4oz) bodyweight as a single dose. This is equivalent to Fenbendazole 100mg/kg. The dose should be administered by mixing the granules with approximately one third of the dog's usual ration. Once the dog has eaten this portion, the remainder of the food may be given. However, any remaining medicated feed should be discarded.

For the treatment of clinical worm infestation in adult dogs, administer 4g of the product per 17.6kg (38lb 8oz) bodyweight daily for 3 days. This is equivalent to Fenbendazole 51mg/kg. The dose should be administered by mixing the granules with approximately one third of the dog's usual ration. Once the dog has eaten this portion, the remainder of the food may be given. However, any remaining medicated feed should be discarded.

In households owning more than one dog, give the granules to each dog individually, ensuring that other dogs do not have access to the treated food during the period of the dose being administered.

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

Benzimidazoles have a wide safety margin.

4.11 Withdrawal periods(s)

Not applicable.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group:
Anthelmintics, Benzimidazoles and related substances

ATCVet code: QP52AC13

5.1 Pharmacodynamic properties

The product 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 helminths by disrupting the formulation 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 helminth 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 for the mammalian tubulin-fenbendazole complex.

5.2 Pharmacokinetic properties

No specific pharmacokinetic studies have been performed with the product.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lactose Monohydrate
Povidone K30
Sodium lauryl sulphate.

6.2 Major 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.

6.5 Nature and composition of immediate packaging

Foil paper sachets containing 4g of granules. Each carton contains 4 x 4g, 3 x 4g sachets.

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

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

Chanelle Pharmaceuticals Manufacturing Ltd
Loughrea
Co. Galway
Ireland.

8. MARKETING AUTHORISATION NUMBER

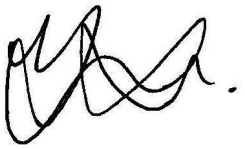
Vm 08749/4056

9. DATE OF THE FIRST AUTHORISATION

05 February 1999

10. DATE OF REVISION OF THE TEXT

June 2022



Approved: 15 June 2022