

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Bob Martin Clear Wormer 880 mg Granules for Dogs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 4 g sachet contains;

Active Substance(s)	mg
Fenbendazole	880

For a full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Granules.
White to off-white granules.

4. CLINICAL PARTICULARS

4.1. Target Species

Dogs.

4.2. Indications for Use, Specifying the Target Species

Bob Martin Clear Wormer is a broad-spectrum anthelmintic for the treatment and control of common roundworms of the gastrointestinal tract.

4.3. Contraindications

None.

4.4. Special Warnings for Each Target Species

Assess bodyweight as accurately as possible before calculating the dosage.

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. Wash hands after use. Avoid inhalation of dust.

4.6. Adverse Reactions (Frequency and Seriousness)

None.

4.7. Use During Pregnancy, Lactation, or Lay

Not recommended. For the treatment of pregnant dogs consult a veterinary surgeon.

4.8. Interaction With Other Medicinal Products, and Other Forms of Interaction

None known.

4.9. Amounts to be Administered and Administration Route

Part sachets should not be used.

Routine treatment of adult dogs:

Administer 1g Bob Martin Clear Wormer per 2.2 kg (5 lbs) bodyweight as a single dose (= 100 mg fenbendazole per kg bodyweight).

Practical dosage recommendations:

2.2 to 4.4 kg (5-10 lbs)	2 grams
4.5 to 8.8 kg (10-20 lbs)	4 grams
8.9 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 bodyweight. The dose should be administered by mixing in the feed.

Treatment should be repeated when natural re-infection 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 6-8 weekly intervals is advisable for dogs in kennels.

Weaned puppies under six months of age:

Administer 1g Bob Martin Clear Wormer per 4.4 kg (10 lbs) bodyweight daily for 3 consecutive days mixed into the feed (= 50 mg fenbendazole per kg bodyweight for 3 days).

Practical dosage recommendations:

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

For dogs/puppies weighing over 22 kg (50 lbs), an extra 1g is required daily for each additional 4.4 kg (10 lbs) bodyweight.

Small or unweaned puppies should be treated with a suitable licensed product up to 12 weeks of age.

Puppies should be treated at 2 weeks of age, 5 weeks of age and again before leaving the breeder's premises. Further treatments are recommended at 8 and 12 weeks of age. Thereafter, frequency of treatment can be reduced unless the pups remain in kennels where infection occurs more readily

4.10. Overdose (Symptoms, Emergency Procedures, Antidotes), If Necessary

No treatment specified. Benzimidazoles have a wide safety margin.

4.11. Withdrawal Period

Not applicable.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Anthelmintic

ATC Vet Code: QP52AC13

5.1. Pharmacodynamic Properties

Fenbendazole, [5-phenylthio)-2-benzimidazole-carbamic] acid methyl ester, belongs to the broad-spectrum anthelmintic class of compounds, the benzimidazoles.

Fenbendazole is believed to act by irreversibly inhibiting glucose uptake by the parasites resulting in depletion of the parasites energy sources, glycogen and ATP, and their consequent death and expulsion.

A relationship exists between plasma concentrations of active anthelmintic metabolites, the duration of high plasma metabolite concentrations and anthelmintic efficacy.

Oxfendazole is a sulphoxide identical to the sulphoxide metabolite of fenbendazole, both are known to be anthelmintically active and metabolically interconvertible.

Much of fenbendazole's anthelmintic activity is attributed to oxfendazole, the latter being more potent.

6. PHARMACEUTICAL PARTICULARS

6.1. List of Excipients

Povidone K30
Maize Starch
Lactose

6.2. Incompatibilities

None known.

6.3. Shelf Life

Shelf life of the veterinary medicinal product as packaged for sale: 4 years

6.4. Special Precautions for Storage

Do not store above 25°C.

6.5. Nature and Composition of Immediate Packaging

Carton containing 4 x 4g or 70 x 4g sachets composed of paper/aluminium/low density polyethylene.

Not all pack sizes may be marketed.

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

Norbrook Laboratories Limited
Station Works
Camlough Road
Newry
Co. Down
BT35 6JP
Northern Ireland

8. MARKETING AUTHORISATION NUMBER


Vm: 02000/4386

9. DATE OF FIRST AUTHORISATION

Date: 16 January 2002

10. DATE OF REVISION OF THE TEXT

Date: April 2014

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