

IRISH MEDICINES BOARD ACT 1995

EUROPEAN COMMUNITIES (ANIMAL REMEDIES) (No. 2) REGULATIONS 2007

(S.I. No. 786 of 2007)

VPA: **10881/006/001**

Case No: 7003633

The Irish Medicines Board in exercise of the powers conferred on it by Animal Remedies (No. 2) Regulations (S.I. No. 786 of 2007) hereby grants to:

The Bob Martin Company

Wemberham Lane, Yatton, Somerset, BS49 4BS, United Kingdom

an authorisation, subject to the provisions of the said Regulations and the general conditions of the attached authorisation, in respect of the Veterinary Medicinal Product:

Bob Martin Easy to Use Wormer Granules for Cats

The particulars of which are set out in Part 1 and Part 2 of the said Schedule. The authorisation is also subject to any special conditions as may be specified in the said Schedule.

The authorisation, unless previously revoked, shall continue in force from **26/06/2007**.

Signed on behalf of the Irish Medicines Board

A person authorised in that behalf by the said Board.

(NOTE: From this date of effect, this authorisation replaces any previous authorisation in respect of this product which is now null and void.)

Part II

Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Bob Martin Easy to Use Wormer Granules for Cats

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Substance:

Fenbendazole 222.2mg/g

Excipients:

For a full list of excipients see section 6.1.

3 PHARMACEUTICAL FORM

Granules

4 CLINICAL PARTICULARS

4.1 Target Species

Cats

4.2 Indications for use, specifying the target species

For the treatment of immature and mature stages of nematodes of the gastro-intestinal and respiratory tracts of cats. It also has an ovicidal effect and is indicated for the following:

For the treatment of gastrointestinal nematodes and cestodes of domestic cats affected with *Ascarid* spp., *Ancylostoma* spp., *Uncinaria* spp., *Trichuris* spp., and *Taenia* spp. Also for the treatment of domestic cats affected with *Aelurostrongylus abstrusus*.

4.3 Contraindications

Do not use in cases of known hypersensitivity to the active ingredient.

4.4 Special warnings for each target species

Do not administer to sick or convalescing animals.

4.5 Special precautions for use

Special precautions for use in animals

If signs of disease persist or appear consult your veterinary surgeon or veterinary practitioner.

Special Precautions to be taken by the Person Administering the 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.

4.6 Adverse reactions (frequency and seriousness)

None known.

4.7 Use during pregnancy, lactation or lay

Bob Martin Easy to Use Wormer for Cats can be safely used in pregnant and young animals, when administered according to the recommended dosing schedules. For the treatment of pregnant cats, seek the advice of 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

For oral administration only, sprinkled onto food.

For the routine treatment of adult (over 6 months old) cats a dosage of 100 mg fenbendazole/kg is recommended.

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

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

For the treatment of clinical worm infestations in cats administer 1g Bob Martin Easy to Use Wormer for Cats per 4.4 kg (10 lbs) bodyweight daily for 3 consecutive days (= 50 mg fenbendazole per kg bodyweight daily for 3 days).

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

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

Not applicable.

4.11 Withdrawal Period(s)

Not applicable.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Anthelmintics, benzimidazoles and related substances

ATCvet Code: QP52AC13

5.1 Pharmacodynamic properties

Bob Martin Easy to Use Wormer Granules for Cats 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 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 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.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lactose
Povidone 30
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

Do not store above 25°C.
Store in dry place.

6.5 Nature and composition of immediate packaging

Foil paper sachets containing 1g of granules. Pack size as follows:
2 x 1g sachets
3 x 1g sachets

Not all pack sizes may be marketed.

6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials

Dispose of unused sachets with the household refuse.
Any unused product or waste materials should be disposed of in accordance with national requirements.

7 MARKETING AUTHORISATION HOLDER

Bob Martin (UK) Ltd.,
Wemberham Lane,
Yatton,
Somerset, BS49 4BS,
United Kingdom.

8 MARKETING AUTHORISATION NUMBER(S)

VPA: 10881/006/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

26th June 2007

10 DATE OF REVISION OF THE TEXT