

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Wormazole 220 mg Granules for dogs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 1g sachet contains :

Active Substance:	mg
Fenbendazole	220

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

Wormazole is a broad spectrum anthelmintic for the treatment and control of mature and immature stages of nematodes and cestodes of the gastrointestinal and respiratory tracts of dogs. Wormazole has also an ovicidal effect on nematode eggs. It is also effective against the protozoa, *Giardia* spp.

Adult Dogs:

For the treatment of adult dogs infected with clinical and subclinical gastrointestinal nematodes and cestode burden detailed below and the protozoa, *Giardia* spp:

Ascarid spp (*Toxocara canis* and *Toxascaris leonina*)

Ancylostoma spp

Trichuris spp

Uncinaria spp

Taenia spp

Puppies:

For the treatment of weaned puppies infected with gastrointestinal nematodes and the protozoa *Giardia* spp.

Pregnant Dogs:

For the treatment of pregnant dogs to reduce prenatal infections of *Toxocara canis* and the transfer of *T. canis* and *Ancylostoma caninum* to their pups via the milk.

Also Wormazole is indicated for the treatment of dogs infected with lungworm *Oslerus (Filaroides) osleri* and protozoa *Giardia* spp.

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

Wormazole is safe for use during pregnancy and lactation, when used in line with recommendations below in 4.9.

4.8 Interaction with other medicinal products and other forms of interaction

None known.

4.9 Amounts to be administered and administration route

Routine treatment of adult dogs:

Administer 1g Wormazole 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 Wormazole 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.

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.

Pregnant dogs:

1g Wormazole per 8.8 kg (20 lbs) bodyweight daily from day 40 of pregnancy continuously to 2 days post-whelping (approximately 25 days) (= 25 mg fenbendazole per kg bodyweight daily).

Practical dosage recommendations:

8.8 kg (20 lbs)	1 gram daily for approximately 25 days
17.6 kg (40 lbs)	2 grams daily for approximately 25 days
26.4 kg (60 lbs)	3 grams daily for approximately 25 days
35.2 kg (80 lbs)	4 grams daily for approximately 25 days
45 kg (100 lbs)	5 grams daily for approximately 25 days

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

Increased dosing for specific indications:

For the treatment of clinical worm infections in adult dogs administer 1g Wormazole per 4.4 kg (10 lbs) bodyweight daily for three consecutive days (= 50 mg fenbendazole per kg bodyweight daily for 3 days).

For the control of lungworm *Oslerus (Filaroides) osleri* in dogs administer 1g Wormazole per 4.4 kg (10 lbs) bodyweight daily for 7 consecutive days (= 50 mg fenbendazole per kg bodyweight daily for 7 days). A repeated course of treatment may be required in some cases.

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: Benzimidazoles

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
Lactose Monohydrate
Maize Starch

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

Wormazole will be presented in 1g (120 x 1g) sachets composed of paper/aluminium/low density polyethylene.

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

Any unused product or waste material should be disposed of in accordance with national requirements.

7. MARKETING AUTHORISATION HOLDER

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

8. MARKETING AUTHORISATION NUMBER(S)

Vm 02000/4158

9. DATE OF FIRST AUTHORISATION

14th August 2001

10. DATE OF REVISION OF THE TEXT

March 2009