

Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Norworm Granules 220 mg/g

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each g contains:

Active substance

Fenbendazole 220 mg

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

Norworm 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. It is also effective as an aid in the control of the protozoon, *Giardia*.

Adult Dogs

For the treatment of adult dogs infected with clinical and subclinical gastrointestinal nematode and cestode burden and as an aid in the control of the protozoon, *Giardia*:

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 as an aid in the control of the protozoon *Giardia*.

Pregnant Bitches

For the treatment of pregnant bitches to reduce prenatal infections of *Toxocara canis* and the transfer of *T. canis* and *Ancylostoma caninum* to their pups via the milk. Also Norworm is indicated for the treatment of dogs infected with lungworm *Oslerus (Filaroides) osleri* and as an aid in the control of the protozoon *Giardia*.

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

Special precaution(s) for use in animals

Direct contact with the product should be kept to a minimum. Wash hands after use.

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.

4.6 Adverse reactions (frequency and seriousness)

None.

4.7 Use during pregnancy, lactation or lay

Norworm is safe for use during pregnancy and lactation, when used in line with data sheet recommendations.

4.8 Interaction with other medicinal products and other forms of interactions

None.

4.9 Amounts to be administered and administration route

Routine treatment of adult dogs

Administer 1g Norworm per 2.2 kg (5lbs) 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 35.2kg (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 1 g is required for each additional 2.2 kg bodyweight. The dose should be administered by mixing into the feed.

Treatment should be repeated when natural reinfection 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 1 g Norworm 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. Treatment may also be required at 8 and 12 weeks of age. Thereafter, frequency of treatment can be reduced unless the pups remain in kennels where infestation occurs more readily.

Pregnant bitches

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

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 bitches weighing over 45 kg, an extra 1 g 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 1 g Norworm per 4.4 kg (10 lbs) bodyweight daily for three consecutive days (= 50mg fenbendazole per kg bodyweight daily for 3 days).

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

For aid in the control of the protozoon *Giardia* administer at a dose of 50 mg/kg daily for 3 consecutive days.

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, fenbendazole.
ATCvet 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.

5.2 Pharmacokinetic particulars

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
Lactose
Maize Starch
Purified Water

6.2 Major incompatibilities

None known.

6.3 Shelf-life

Shelf-life of the veterinary medicinal product as packaged for sale: 2 years

6.4 Special precautions for storage

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

6.5 Nature and composition of immediate packaging

Supplied in sachets comprised of paper/aluminium/LDPE containing 1 g, 2 g, 4 g or 5 g per sachet. Sachets are supplied in multipack cartons of 120 x 1 g, 100 x 2 g, 70 x 4 g, 5 x 1 g, 5 x 2 g, 4 x 4 g, 5 x 5 g and 60 x 5 g.

Not all pack sizes may be marketed.

6.6 Special precautions for the disposal of unused veterinary medicinal products 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 (Ireland) Limited
Rossmore Industrial Estate
Monaghan
Ireland

8 MARKETING AUTHORISATION NUMBER(S)

VPA22664/050/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 30 April 1999

Date of last renewal: 29 April 2009

10 DATE OF REVISION OF THE TEXT

February 2019