

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE 1G LABEL

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Wormazole 220 mg Granules for dogs

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

1 gram Wormazole contains 220 mg fenbendazole.

3. PHARMACEUTICAL FORM

Granules

Wormer for dogs

4. PACKAGE SIZE

1 gram

5. TARGET SPECIES

Dogs

6. INDICATION(S)

For the treatment of adult dogs infected with roundworms and tapeworms (*Toxocara canis*, *Toxascaris leonina*, *Ancylostoma* spp, *Trichuris* spp *Uncinaria* spp and *Taenia* spp). Also effective against lungworms *Oslerus (Filaroides) osleri* and protozoa *Giardia* spp.

For the treatment of weaned puppies infected with roundworms and puppies infected with protozoa *Giardia* spp. For the treatment of pregnant bitches to reduce prenatal infections with *Toxocara canis* and the transfer of *T. canis* and *Ancylostoma caninum* to their pups via the milk.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

MIXES INTO FEED

DOSAGE

This 1 gram sachet treats:

Routine treatment of adult dogs - 1 sachet Wormazole per 2.2 kg (5 lbs) bodyweight on a single occasion.

Weaned puppies under 6 months of age, protozoa Giardia infections - 1 sachet per 4.4 kg (10 lbs) bodyweight daily for 3 days.

Pregnant bitches - 1 sachet per 8.8 kg (20 lbs) daily from day 40 of pregnancy to 2 days post whelping (approximately 25 days).

Lungworm in dogs - 1 sachet per 4.4 kg (10 lbs) bodyweight daily for 7 days. A repeat treatment may be necessary.

Wormazole granules are odourless and tasteless and are readily consumed by animals.

Treatment should be repeated when natural reinfestation of animals with parasitic worms occurs.

Treatment of adult dogs is advisable 2 to 4 times a year.

Puppies should be treated at 2 weeks of age and again at 5 weeks of age. Further treatments are recommended at 8 and 12 weeks of age.

Thereafter frequency of treatment can be reduced unless the pups are housed in a kennel environment where reinfection occurs more readily.

Assess bodyweight as accurately as possible before calculating the dosage

8. SPECIAL WARNING(S), IF NECESSARY

USER SAFETY:

Direct contact with the skin should be kept to a minimum. Wash hands after use. Avoid inhalation of dust.

9. EXPIRY DATE

DOM:

EXP: dd/mm/yy

10. SPECIAL STORAGE CONDITIONS

Do not store above 25°C.

Keep sachets in outer carton.

11. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Dispose of empty packaging and any remaining product in the household refuse

12. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE

FOR ANIMAL TREATMENT ONLY

NFA-VPS

May be supplied without prescription by a suitable Qualified person.

13. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

KEEP OUT OF THE REACH AND SIGHT OF CHILDREN

14. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Manufactured by:

Norbrook Laboratories Limited

Newry

Co. Down, BT35 6JP

Distributed by:

Norbrook Laboratories Limited

1 Saxon Way East
Oakley Hay Industrial Estate
Corby
Northamptonshire
NN18 9EX
United Kingdom

15. MARKETING AUTHORISATION NUMBER(S)

ManA 2000

Vm: 02000/4158

16. MANUFACTURER'S BATCH NUMBER

B.N.:

PARTICULARS TO APPEAR ON THE OUTER PACKAGE 1G CARTON

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Wormazole 220 mg Granules for dogs

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

A granulate formulation of fenbendazole as a ready to use oral anthelmintic.

1 gram Wormazole contains 220 mg fenbendazole.

3. PHARMACEUTICAL FORM

Granules

Wormer for dogs

4. PACKAGE SIZE

1g x 120 sachets

5. TARGET SPECIES

Dogs

6. INDICATION(S)

For the treatment of adult dogs infected with roundworms and tapeworms (*Toxocara canis*, *Toxascaris leonina*, *Ancylostoma* spp, *Trichuris* spp *Uncinaria* spp and *Taenia* spp). Also effective against lungworms *Oslerus (Filaroides) osleri* and protozoa *Giardia* spp.

For the treatment of weaned puppies infected with roundworms and puppies infected with protozoa *Giardia* spp. For the treatment of pregnant bitches to reduce prenatal infections with *Toxocara canis* and the transfer of *T. canis* and *Ancylostoma caninum* to their pups via the milk.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Part used sachets should not be administered.

Recommended doses:

Routine treatment of adult dogs: 1 g Wormazole per 2.2 kg (5 lbs) bodyweight as a single dose (= 100mg fenbendazole per kg bodyweight)

Weight of animal	Dose required
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

Treatment should be repeated 2 to 4 times per year as natural re-infection with worms occurs. More frequent treatment at 6 to 8 weekly intervals is advisable for dogs in kennels.

Increased dosing for specific infections:

For the control of lungworm *Oslerus (Filaroides) osleri* in dogs - 1 gram Wormazole per 4.4 kg (10 lbs) bodyweight daily for 7 consecutive days. A repeat course of treatment may sometimes be required.

Weaned puppies under six months of age - 1 gram Wormazole per 4.4 kg (10 lbs) bodyweight daily for 3 consecutive days.

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 can be reduced unless the pups are housed in kennels where reinfection occurs more readily.

Recommended doses:

Weaned puppies under 6 months of age: 1 g Wormazole per 4.4kg (10 lbs) bodyweight daily for three consecutive days (= 50mg fenbendazole per kg bodyweight for 3 days)

Weigh of animal in kg (lbs)	Daily dose for 3 days	Total quantity of Wormazole required for 3 days
2.2 - 4.4 kg (5-10 lbs)	1 gram per day	3 grams
4.5 - 8.8 kg (10-20 lbs)	2 grams per day	6 grams
8.9 - 13.2 kg (20-29 lbs)	3 grams per day	9 grams
13.3 - 17.6 kg (30-40 lbs)	4 grams per day	12 grams

Pregnant bitches:

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

Recommended doses:

Pregnant bitches:

Birth Weight	Daily Dose	Total quantity of Wormazole required for approximately 25 days
8.8 kg (20 lbs)	1 gram	25 grams
17.6 kg (40 lbs)	2 grams	50 grams
26.4 kg (60 lbs)	3 grams	75 grams
35.2 kg (80 lbs)	4 grams	100 grams

8. SPECIAL WARNING(S), IF NECESSARY

Assess bodyweight as accurately as possible before calculating the dosage.

Wormazole Granules are odourless and tasteless and are readily consumed by animals.

USER WARNINGS:

Direct contact with the skin should be kept to a minimum.

Wash hands after use. Avoid inhalation of dust.

9. EXPIRY DATE

DOM:

EXP: dd/mm/yy

10. SPECIAL STORAGE CONDITIONS

Do not store above 25°C.

Keep sachets in outer carton.

11. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Dispose of empty packaging and any remaining product in the household refuse

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FOR ANIMAL TREATMENT ONLY

NFA-VPS

May be supplied without prescription by a suitable Qualified person.

UK AUTHORISED VETERINARY MEDICINAL PRODUCT

13. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

KEEP OUT OF THE REACH AND SIGHT OF CHILDREN

14. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Manufactured by:

Norbrook Laboratories Limited
Newry
Co. Down, BT35 6JP

Distributed by:

Norbrook Laboratories Limited
1 Saxon Way East
Oakley Hay Industrial Estate
Corby
Northamptonshire
NN18 9EX
United Kingdom

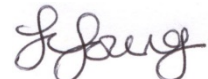
15. MARKETING AUTHORISATION NUMBER(S)

ManA 2000
Vm: 02000/4158

16. MANUFACTURER'S BATCH NUMBER

B.N.:

Approved: 03/08/2017

A handwritten signature in black ink, appearing to read 'J. Berg', is written below the approval date.