

A. LABELLING

<PARTICULARS TO APPEAR ON THE OUTER PACKAGE>

CARTON

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Fenbendazole Wormer Granules 888 mg for Adult Dogs

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each sachet contains 888.8 mg fenbendazole.

3. PHARMACEUTICAL FORM

Granules

4. PACKAGE SIZE

1, 2, 3, 4 or 5 x 4g

5. TARGET SPECIES

Adult Dogs

6. INDICATION(S)

Dogs

For the treatment of immature and mature stages of *Toxacara canis* and *Taenia hydatigena*.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Dosage and Administration:

For oral administration only; sprinkled onto food.

For the routine treatment of adult dogs a dosage of 100 mg/kg is recommended.

This equates to approximately 1 whole sachet per 8 kg bodyweight (2 sachets for 16 kg bodyweight; 3 sachets for 24 kg bodyweight etc.).

Sachets must not be divided and stored for future use. If necessary, a suitable alternative product must be selected.

To ensure administration of a correct dose, body weight should be determined as accurately as possible.

Discard any remaining medicated feed.

8. WITHDRAWAL PERIOD

N/A

9. SPECIAL WARNING(S), IF NECESSARY

For advice on the treatment of pregnant dogs please consult your veterinary surgeon. If signs of disease persist or appear consult your veterinary surgeon. The product can cause irritation to the skin, eyes and lungs. Direct contact with the skin should be kept to a minimum. Avoid inhalation of granule dust. Wash hands after use. Avoid contact with the eyes. In case of accidental eye contact, irrigate the eyes with plenty of clean water. If irritation persists, seek medical advice. Only use for the bodyweight of animal recommended. The entire contents of the sachet must be directly sprinkled onto food as a single dose. Discard any uneaten medicated feed.

10. EXPIRY DATE

<EXP >

11. SPECIAL STORAGE CONDITIONS

Store in a dry place. Keep sachets in the outer carton.

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: read package leaflet.

13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

For animal treatment only

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

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

MA Holder:
C&H Generics Ltd, c/o Michael McEvoy and Co, Seville House, New Dock Street, Galway, Ireland

16. MARKETING AUTHORISATION NUMBER

Vm 40162/4005

Legal Category:

AVM-GSL

17. MANUFACTURER’S BATCH NUMBER

<BN>

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Sachet 4g

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Fenbendazole Wormer Granules 888 mg for Adult Dogs

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Each sachet contains 888.8 mg fenbendazole.

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

4g

4. ROUTE(S) OF ADMINISTRATION

Dosage and Administration:

For oral administration only; sprinkled onto food.
For the routine treatment of adult dogs a dosage of 100 mg/kg is recommended.
This equates to approximately 1 whole sachet per 8 kg bodyweight (2 sachets for 16 kg bodyweight; 3 sachets for 24 kg bodyweight etc.).

Sachets must not be divided and stored for future use. If necessary, a suitable alternative product must be selected.

To ensure administration of a correct dose, body weight should be determined as accurately as possible.

Discard any remaining medicated feed.

5. WITHDRAWAL PERIOD

N/A

6. BATCH NUMBER

<BN>

7. EXPIRY DATE

<EXP >

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

PACKAGE LEAFLET

Fenbendazole Wormer Granules 888 mg for Adult Dogs

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

MA Holder:

C&H Generics Ltd, c/o Michael McEvoy and Co, Seville House, New Dock Street, Galway, Ireland

Manufacturer responsible for batch release:

Chanelle Pharmaceuticals Manufacturing Ltd., Loughrea, Co. Galway, Ireland.

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Fenbendazole Wormer Granules 888 mg for Adult Dogs

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

Each 4 g sachet contains a free flowing white to greyish white granular powder with 888.8 mg fenbendazole.

4. INDICATION(S)

What this product does:

This product kills *Toxacara canis* (a common roundworm) and *Taenia hydatigena* (a common tapeworm) which can infect dogs.

5. CONTRAINDICATIONS

For treatment of pregnant dogs seek the advice of a veterinary surgeon.

Do not use in cases of known hypersensitivity to the active substance or any other ingredient(s).

6. ADVERSE REACTIONS

If symptoms of disease persist or appear, consult your veterinary surgeon.

If you notice any serious effects or other effects not mentioned in this package leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Dogs

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

For oral administration only; sprinkled onto food.

For the routine treatment of adult dogs a dosage of 100 mg/kg is recommended.

This equates to approximately 1 whole sachet per 8 kg bodyweight (2 sachets for 16 kg bodyweight; 3 sachets for 24 kg bodyweight etc.).

Sachets must not be divided and stored for future use. If necessary, a suitable alternative product must be selected.

9. ADVICE ON CORRECT ADMINISTRATION

Give this medicine by sprinkling the granules onto the animal's usual food. After treatment, the pet may become naturally reinfected with worms. Speak to your vet to determine when to treat your animal again.

To ensure administration of a correct dose, body weight should be determined as accurately as possible. Discard any remaining medicated feed.

If you consider that this product has not worked or has caused your dog to become unwell, please seek the advice of a veterinary surgeon and write to the address indicated below.

10. WITHDRAWAL PERIOD

N/A

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

Add to feed immediately before administration.

Discard any remaining medicated feed.

Store in a dry place. Keep the sachets in the outer carton.

Please retain this leaflet for future reference if you have not used all sachets provided in one carton.

Do not use this veterinary medicinal product after the expiry date which is stated on the sachet and carton after 'EXP'. The expiry date refers to the last day of that month.

12. SPECIAL WARNING(S)

The product can cause irritation to the skin, eyes and lungs. Direct contact with the skin should be kept to a minimum. Avoid inhalation of granule dust. Wash hands after use. Avoid contact with the eyes. In case of accidental eye contact, irrigate the eyes with plenty of clean water. If irritation persists, seek medical advice. Only use for the bodyweight of animal recommended. The entire contents of the sachet must be directly sprinkled onto food as a single dose. Discard any uneaten medicated feed.

For treatment of pregnant dogs seek the advice of a veterinary surgeon.
If symptoms of disease persist or appear, consult your veterinary surgeon.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements. Discard any uneaten medicated feed.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

15. OTHER INFORMATION

Cartons containing 1, 2, 3, 4 or 5 sachets.
Not all pack sizes may be market

Approved: 06/10/2016

