

PARTICULARS TO APPEAR ON <THE IMMEDIATE PACKAGE>

{Carton }

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Beaphar Worming Granules for Dogs and Puppies, 666 mg/sachet

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Active ingredient:

Each 3g sachet contains 666 mg Fenbendazole

3. PHARMACEUTICAL FORM

Granules

4. PACKAGE SIZE

Contains: Four sachets

This pack will treat a 6.6kg (15lb) dog on four occasions or a 26.4kg (60lb) dog once.

5. TARGET SPECIES

Dogs

6. INDICATION(S)

[Optional. In case of space restriction and if the indication is clear from the name of the product, the indication should not be repeated]

Recommended for the effective control of all common roundworms and their eggs.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

DIRECTIONS

Weigh your dog carefully and calculate the number of sachets needed. Sprinkle the contents of the sachet(s) onto your dog's food and mix immediately before feeding. Give less food than usual to make sure it is all eaten. Treat dogs separately and make sure only the dog to be treated has access to the food.

PUPPIES

(over 12 weeks but under 6 months and weighing at least 6.6kg)

Give the recommended number of sachets EACH DAY for 3 CONSECUTIVE DAYS:

6.6 to 13.2kg (15-30lb) 1 sachet

13.3 to 26.4kg (30.1-60lb) 2 sachets

ADULT DOGS (over 24 weeks)

Treat every 3-6 months. Weigh your dog as accurately as possible and then use the

following number of sachets as a SINGLE dose:

3.3 to 6.6kg (7.5-15lb) 1 sachet

6.7 to 13.2kg (15.1-30lb) 2 sachets

13.3 to 19.8kg (30.1-45lb) 3 sachets

19.9 to 26.4kg (45.1-60lb) 4 sachets

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

8. WITHDRAWAL PERIOD

N/A

9. SPECIAL WARNING(S), IF NECESSARY

<User Warnings>

For the treatment of sick or pregnant dogs, or puppies under 12 weeks of age, consult your Veterinary Surgeon.

PRECAUTIONS

Direct contact with the skin should be kept to a minimum. Avoid inhalation of granule dust. Wash hands after use. Add to feed immediately before administration. Discard any remaining medicated feed.

10. EXPIRY DATE

EXP: end {month/year}

11. SPECIAL STORAGE CONDITIONS

Store in a dry place.

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

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

13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE [*Distribution category*]

For animal treatment only

AVM-GSL

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

Keep out of reach of children

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Sinclair Animal & Household Care Ltd, Gainsborough, DN21 2QB UK

16. MARKETING AUTHORISATION NUMBER(S)

Vm <number>

Vm 16516/4025

17. MANUFACTURER'S BATCH NUMBER

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING
UNITS {NATURE/TYPE}

3 g sachet

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Beaphar Worming Granules for Dogs and Puppies, 666 mg/sachet

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Each 3g sachet contains 666mg Fenbendazole

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

3 g

4. ROUTE(S) OF ADMINISTRATION

Add to feed immediately before administration.

5. WITHDRAWAL PERIOD

N/A

6. BATCH NUMBER

B.N.:

7. EXPIRY DATE

Exp; end

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only

Beaphar Worming Granules for Dogs and Puppies, 666 mg/sachet, are effective against roundworms and their eggs. The contents of this sachet will treat dogs and weaned puppies by sprinkling into their food.

Directions for use: follow the directions on the carton.

Precautions: read the carton carefully. If signs of disease persist or appear, consult your Veterinary Surgeon. Direct contact with the skin should be kept to a minimum. Avoid inhalation of granule dust. Wash hands after use. Store in a dry place. Add to feed immediately before administration. Discard any remaining medicated feed. Dispose of any empty packaging and any remaining product in the household refuse.

For animal treatment only. Keep out of reach of children.

Each 3g sachet contains 666mg Fenbendazole

Vm 16516/4025

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS {NATURE/TYPE}

Not applicable

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

2. NAME OF THE MARKETING AUTHORISATION HOLDER

3. EXPIRY DATE

4. BATCH NUMBER

5. THE WORDS “FOR ANIMAL TREATMENT ONLY”

PARTICULARS TO APPEAR ON THE IMMEDIATE DILUENT LABEL

Not applicable

1. NAME OF THE DILUENT

The 'trade' name with a brief description or a more describing way of naming (Solvent /diluent for type of vaccine it can be used with or properties of the diluent).

2. CONTENT BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

3. ROUTES OF ADMINISTRATION

[According to "Standard terms" published by the Council of Europe. See also QRD reference document "Tables of non-standard abbreviations".]

Read the package leaflet before use.

4. STORAGE CONDITIONS

<Do not store above <25 °C> <30 °C>.>

<Store below <25 °C> <30 °C>.>

<Store in a refrigerator.>

<Store and transport refrigerated.>*

<Store in a freezer.>

<Store and transport frozen.>**

<Do not <refrigerate> <or> <freeze>.>

<Protect from frost.>***

<Store in the original <container><package>.>

<Keep the {container}**** tightly closed.>

<Keep the {container}**** in the outer carton.>

<in order to protect from <light> <and> <moisture>>

<Protect from light.>

<Store in a dry place.>

<Protect from direct sunlight.>

<This veterinary medicinal product does not require any special storage conditions.>

<This veterinary medicinal product does not require any special temperature storage conditions.>

5. BATCH NUMBER

<Batch> <Lot> <BN> {number}

6. EXPIRY DATE

<EXP {month/year}>

7. THE WORDS “FOR ANIMAL TREATMENT ONLY”

[Include information under these headings as it appears in the SPC]

PACKAGE LEAFLET FOR:

Not applicable

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

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

4. INDICATION(S)

5. CONTRAINDICATIONS

6. ADVERSE REACTIONS

7. TARGET SPECIES

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

9. ADVICE ON CORRECT ADMINISTRATION

10. WITHDRAWAL PERIOD(S)

11. SPECIAL STORAGE PRECAUTIONS

[Pharmaceuticals ONLY - The following statement should be included if there is an in-use shelf life (example: solution for injection)]

12. SPECIAL WARNING(S)

<User Warnings>

[Immunologicals ONLY - For injectables containing mineral oil, the following statement should be included:]

<To the user:

This product contains mineral oil. Accidental injection/self injection may result in severe pain and swelling, particularly if injected into a joint or finger, and in rare cases could result in the loss of the affected finger if prompt medical attention is not given.

If you are accidentally injected with this product, seek prompt medical advice even if only a very small amount is injected and take the package insert with you.

If pain persists for more than 12 hours after medical examination, seek medical advice again.

To the physician:

This product contains mineral oil. Even if small amounts have been injected, accidental injection with this product can cause intense swelling, which may, for example, result in ischaemic necrosis and even the loss of a digit. Expert, PROMPT, surgical attention is required and may necessitate early incision and irrigation of the injected area, especially where there is involvement of finger pulp or tendon.>

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

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

<15. OTHER INFORMATION>

[Distribution category]

Vm <number>

MINIMUM PARTICULARS TO APPEAR ON THE LABEL WHERE THERE IS NO PACKAGE LEAFLET, E.g. Concertina Labels. {NATURE/TYPE}

[The guidance contained below is national specific only and should be used in addition to EU QRD template guidance for both the Package Leaflet AND the Outer/Immediate package, available on the EMA website.]

Not applicable

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

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

4. PHARMACEUTICAL FORM

5. PACKAGE SIZE

6. INDICATION(S)

[Optional. In case of space restriction and if the indication is clear from the name of the product, the indication should not be repeated]

7. CONTRAINDICATIONS

8. ADVERSE REACTIONS

9. TARGET SPECIES

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

11. ADVICE ON CORRECT ADMINISTRATION

12. WITHDRAWAL PERIOD

13. SPECIAL STORAGE PRECAUTIONS

Keep the container in the outer carton.

[Pharmaceuticals ONLY - The following statement should be included if there is an in-use shelf life (example: solution for injection)]

<When the container is broached/opened for the first time, using the in-use shelf-life which is specified on this package leaflet, the date on which any product remaining in the container should be discarded should be determined. This discard date should be written in the space provided.>

14. SPECIAL WARNING(S)<User Warnings>

15. EXPIRY DATE

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

17. DATE ON WHICH THE LABEL WAS LAST APPROVED

[It is mandatory for Exceptional Marketing Authorisations and recommended for others that the following reference to the VMD Website is included:]

<Find more product information by searching for the Product Information Database 'PID' on www.gov.uk.>

18. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

[Distribution category]

POM-V

POM-VPS

NFA-VPS

AVM-GSL

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

20. MARKETING AUTHORISATION NUMBER(S)

Vm <number>

21. MANUFACTURER’S BATCH NUMBER

<22. OTHER INFORMATION>

Approved: 03/11/2017

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