

PARTICULARS TO APPEAR ON <THE IMMEDIATE PACKAGE>

{Carton}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Beaphar Easy One Dose Worming Tablets for Small Dogs and Puppies, 100 mg
Film-coated Tablets

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each tablet contains 100mg of Nitroscanate.

3. PHARMACEUTICAL FORM

Film-coated Tablets

4. PACKAGE SIZE

3 x 100 mg film-coated tablets.

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]

For the control of Roundworm, common Tapeworm and Hookworm.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

How do I use it? Weigh your pet carefully and calculate the number of tablets needed. Give the tablet(s) in the morning, when your dog's stomach is empty, with about a fifth of your dog's daily food. Do not feed again until eight hours later. The tablets are film coated and must be fed whole, not broken or divided. Treat dogs separately and make sure only the dog to be treated has access to the food. Puppies (up to 24 weeks) treat at 12, 16 and 24 weeks as a precaution against Roundworm. An alternative worming product must be used in younger puppies. Nursing bitches should be treated at the same time and as frequently as puppies up to 12 weeks of age. Adult Dogs (over 24 weeks) treat every 3-6 months. Fleas transmit the most common Tapeworm, so to reduce Tapeworm infection effective flea control is required.

Dosing Instructions

Give one tablet for each 2kg (4lb 6oz) of bodyweight.

2.1kg (4lb 10oz) – 4kg (8lb 13oz) two tablets.

4.1kg (9lb) – 6kg (13lb 3oz) three tablets.

For dogs weighing more than 8kg (17.5lb), use Beaphar Easy One Dose Worming Tablets For Dogs, 500mg film-coated tablets.

If symptoms of disease persist or appear consult your Veterinary Surgeon.

8. WITHDRAWAL PERIOD

N/A

9. SPECIAL WARNING(S), IF NECESSARY

<User Warnings>

Contra-indications

Do not use in dogs weighing less than 2 kg.

Do not repeat treatment if vomiting occurs shortly after dosing.

Do not administer if your pet is sick or recovering from an illness.

Do not use in known cases of hypersensitivity to the active substance or to any of the excipients. If a hypersensitivity reaction occurs treatment should be discontinued.

Precautions

The product should not be administered to puppies less than 12 weeks old owing to the need to restrict food intake at the time of administration.

For animal treatment only. Keep out of reach of children. This product can be an irritant to the skin and eyes. Tablets are film-coated and should not be broken or divided. Wash hands after use. For more information see enclosed leaflet.

10. EXPIRY DATE

EXP end: {month/year}

11. SPECIAL STORAGE CONDITIONS

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

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

Dispose of empty packaging and any remaining tablets 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 the sight and reach of children

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

MA Holder
Sinclair Animal and Household Care Ltd
Ropery Road
Gainsborough
Lincolnshire
DN21 2QB

Distributed by
Sinclair Animal and Household Care Ltd
Ropery Road
Gainsborough
Lincolnshire
DN21 2QB

16. MARKETING AUTHORISATION NUMBER

Vm 16516/4013

17. MANUFACTURER’S BATCH NUMBER

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

Not applicable

- 1. NAME OF THE VETERINARY MEDICINAL PRODUCT**
- 2. QUANTITY OF THE ACTIVE SUBSTANCE(S)**
- 3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES**
- 4. ROUTE(S) OF ADMINISTRATION**
- 5. WITHDRAWAL PERIOD**
- 6. BATCH NUMBER**
- 7. EXPIRY DATE**
- 8. THE WORDS “FOR ANIMAL TREATMENT ONLY”**

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

{NATURE/TYPE}

Foil blister

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

NITROSCANATE 100mg

2. NAME OF THE MARKETING AUTHORISATION HOLDER

Vm 16516/4013

3. EXPIRY DATE

EXP: mm/yyyy

4. BATCH NUMBER

BN: A12345

5. THE WORDS “FOR ANIMAL TREATMENT ONLY”

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:

**Beaphar Easy One Dose Worming Tablets for Small Dogs and Puppies, 100 mg
Film-coated Tablets**

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

MA Holder
Sinclair Animal and Household Care Ltd
Ropery Road
Gainsborough
Lincolnshire
DN21 2QB

Distributed by
Sinclair Animal and Household Care Ltd
Ropery Road
Gainsborough
Lincolnshire
DN21 2QB

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Beaphar Easy One Dose Worming Tablets for Small Dogs and Puppies, 100 mg
Film-coated Tablets

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

Each tablet contains Nitroscanate 100mg.

4. INDICATION(S)

For the treatment the following nematodes (roundworms) and cestodes (tapeworms): Nematodes: *Toxocara canis*, *Toxascaris leonina*, *Uncinaria stenocephala*, *Ancylostoma caninum*. Cestodes: *Taenia hydatigena*, *Taenia pisiformis*, and *Dipylidium caninum*.

5. CONTRAINDICATIONS

Do not use in dogs weighing less than 2 kg.
Do not repeat treatment if vomiting occurs shortly after dosing.
Do not administer if your pet is sick or recovering from an illness.
Do not use in known cases of hypersensitivity to the active substance or to any of the excipients. If a hypersensitivity reaction occurs treatment should be discontinued.

6. ADVERSE REACTIONS

During the post-marketing surveillance, transient gastrointestinal signs (vomiting and diarrhoea); systemic sign (lethargy) and neurological sign (ataxia) have been observed very rarely.

The frequency of adverse reactions is defined using the following convention:

- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

7. TARGET SPECIES

Dogs

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

Dosing Instructions

Dose: For treatment of roundworm and tapeworm in small dogs and puppies give 1 x 100mg tablet per 2kg (4.4lb) bodyweight, equivalent to 50mg nitroscanate/kg bodyweight.

Follow the dosage chart below:

Dog's weight	Example breed	Number of tablets
2.1kg (4lb 10oz) – 4kg (8lb 13oz)	Miniature Dachshund	Two
4.1kg (9lb) – 6kg (13lb 3oz)	Miniature Poodle	Three

For dogs weighing more than 8kg (17.5lb) use Beaphar Easy One Dose Worming Tablets for Dogs, 500mg film-coated tablets.

How Do I Use It?

The product should be administered orally in the morning after overnight fasting with approximately one-fifth of the daily food ration. The tablet(s) should be given whole. Tablets are film-coated and should not be broken or divided.

To reduce the risk of vomiting, it is recommended that the remaining food ration is withheld for at least 8 hours afterwards.

9. ADVICE ON CORRECT ADMINISTRATION

Beaphar Easy One Dose Worming Tablets for Small Dogs & Puppies, 100mg will kill Tapeworms, Roundworms and Hookworms. Beaphar Easy One Dose Worming Tablets for Small Dogs & Puppies, 100mg can safely be used on puppies from 12

weeks of age. Puppies should be dosed at 12, 16 and 24 weeks. Adult dogs should be dosed every 3 to 6 months as a preventative measure. If signs of disease persist or appear, consult your Veterinary Surgeon. There is no permanent treatment for these worms, therefore routine worming is essential, especially if the animal is suffering from a flea infestation. Worms are very common parasites that can cause irritation and suffering and could hinder development or lead to serious illness. Symptoms vary, but can include traces of blood or worms in the faeces, ravenous appetite without a corresponding increase in weight, attempts at vomiting and a marked deterioration in coat condition and breath.

Further Information:

1. It is recommended that adult dogs should be wormed routinely 2 – 4 times a year. Since the most common tapeworm of the dog (*Dipylidium Caninum*) is transmitted by a flea and has a very short pre-patent period, it is important to pay attention to flea control to reduce the incidence of tapeworm in your pet.
2. It is important to worm young puppies very regularly for roundworm with a suitable product. Beaphar Easy One Dose Worming Tablets for Small Dogs & Puppies, 100mg can be used at 12, 16 and 24 weeks of age. Nursing bitches should be treated at the same time and as frequently as puppies up to 12 weeks of age. Thereafter the adult worming regime of 2 – 4 times a year is recommended.

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)]

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

12. SPECIAL WARNING(S)

<User Warnings>

For Animal Treatment Only

This product can be an irritant to the skin and eyes.
Tablets are film-coated and should not be broken or divided. Wash hands after use.

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

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

14. PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

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

<15. OTHER INFORMATION>

[Distribution category]

AVM-GSL

Vm <number>

Vm 16516/4013

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

Vm 16516/4013

21. MANUFACTURER’S BATCH NUMBER

<22. OTHER INFORMATION>

Gavin Hall

Approved 12 June 2024