

## LABELLING

### <PARTICULARS TO APPEAR ON THE OUTER PACKAGE>

#### CARTON

**Beaphar One Dose Small Dog Wormer 100mg Nitroscanate Film-Coated Tablets**

**3, 4 & 6 tablets only**

#### 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Beaphar One Dose Small Dog Wormer 100mg Nitroscanate Film-Coated Tablets

#### 2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each tablet contains Nitroscanate 100 mg.

#### 3. PHARMACEUTICAL FORM

Tablets

#### 4. PACKAGE SIZE

3 tablets

4 tablets

6 tablets

#### 5. TARGET SPECIES

Dogs

#### 6. INDICATION(S)

Easy to use

Kills Tapeworm, Roundworm and Hookworm in a single dose

#### 7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use

**Directions for Use:**

Give the required number of tablets first thing in the morning when your dog's stomach is empty, with about one fifth of their daily food ration. The tablets should be given whole. This product can be an irritant to the skin and eyes. Tablets are film-coated and should not be broken or divided. Give your dog their remaining food in the evening, at least eight hours after the wormer dose.

**Dosage:** The dose of the product for the treatment of dogs is nitroscanate 50 mg/kg bodyweight, which is equivalent to 1 x 100 mg tablet per 2 kg (4.4 lb) bodyweight.

**8. WITHDRAWAL PERIOD**

N/A

**9. SPECIAL WARNING(S), IF NECESSARY**

Read the package leaflet before use.

If vomiting does occur following treatment, do not repeat the dose.

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 or any other adverse reaction occurs, cease treatment.

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

Do not use in dogs weighing less than 2 kg.

Do not use in puppies less than 6 months old because of the need to restrict food intake at the time of administration.

**10. EXPIRY DATE**

<EXP >

**11. SPECIAL STORAGE CONDITIONS**

Store in a dry place. Do not store above 25°C. Keep blister strips in outer carton.

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

Dispose of 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**

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**

**M.A. Holder:** Chanelle Animal Health Ltd., 7 Rodney St., Liverpool L1 9HZ, UK.

**Distributor:** Beaphar UK Ltd., Rook Tree Farm, Withersfield Road, Great Wratting, Suffolk, CB9 7HD.

**16. MARKETING AUTHORISATION NUMBER**

Vm: 11990/4009

Legal category

AVM-GSL

**17. MANUFACTURER’S BATCH NUMBER**

<BN>

## LABELLING

**<PARTICULARS TO APPEAR ON THE OUTER PACKAGE>**

**CARTON**

**Beaphar One Dose Small Dog Wormer 100mg Nitroscanate Film-Coated  
Tablets  
100 tablets only**

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Beaphar One Dose Small Dog Wormer 100mg Nitroscanate Film-Coated Tablets

**2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES**

Each tablet contains Nitroscanate 100 mg.

**3. PHARMACEUTICAL FORM**

Tablets

**4. PACKAGE SIZE**

100 tablets

**5. TARGET SPECIES**

Dogs

**6. INDICATION(S)**

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

**7. METHOD AND ROUTE(S) OF ADMINISTRATION**

Read the package leaflet before use

**Dosage:** The dose of the product for the treatment of dogs is nitroscanate 50 mg/kg bodyweight, which is equivalent to 1 x 100 mg tablet per 2 kg (4.4 lb) bodyweight.

**Administration:** The tablet(s) should be administered orally in the morning after overnight fasting with approximately one-fifth of the daily food ration. The remaining food ration should be withheld for at least 8 hours.

## 8. WITHDRAWAL PERIOD

N/A

## 9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use

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

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 with the product should be discontinued.

The product should not be administered to puppies less than 6 months old, owing to the need to restrict food intake at the time of administration.

Do not use in dogs weighing less than 2 kg.

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

### Further information:

i) The product is not indicated for the treatment of *Trichuris vulpis*

ii) 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.

## 10. EXPIRY DATE

<EXP >

## 11. SPECIAL STORAGE CONDITIONS

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

Keep blister strips in outer carton.

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

Dispose of 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**

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**

**M.A. Holder:** Chanelle Animal Health Ltd., 7 Rodney St., Liverpool L1 9HZ, UK.

**Distributor:** Beaphar UK Ltd., Rook Tree Farm, Withersfield Road, Great Wratting, Suffolk, CB9 7HD.

**16. MARKETING AUTHORISATION NUMBER**

Vm: 11990/4009

Legal category

AVM-GSL

**17. MANUFACTURER’S BATCH NUMBER**

<BN>

**MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS**

{NATURE/TYPE}

**BLISTERS**

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Beaphar One Dose Small Dog Wormer 100mg Nitroscanate Film-Coated Tablets  
Nitroscanate 100mg

**2. NAME OF THE MARKETING AUTHORISATION HOLDER**

Chanelle.

**3. EXPIRY DATE**

<EXP >

**4. BATCH NUMBER**

<BN>

**5. THE WORDS “FOR ANIMAL TREATMENT ONLY”**

For animal treatment only.

**PACKAGE LEAFLET**  
**(For pack size of 3, 4 & 6 tablets only)**

Beaphar One Dose Small Dog Wormer 100mg Nitroscanate Film-Coated Tablets.

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

**M.A Holder:** Chanelle Animal Health Ltd., 7 Rodney St., Liverpool L1 9HZ, UK.

**Manufacturer responsible for batch release:**

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

Beaphar B.V., Oude Linderteseweg 9, 8102 EV Raalte, The Netherlands.

Sinclair Animal and Household Care Limited, Ropery Road, Gainsborough, Lincolnshire, DN21 2QB, United Kingdom.

**2. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Beaphar One Dose Small Dog Wormer 100mg Nitroscanate Film-Coated Tablets  
Nitroscanate

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

Each tablet contains Nitroscanate 100 mg.

**4. INDICATION(S)**

For the treatment of the following nematodes (roundworms) and cestodes (tapeworms):

Nematodes: *Toxo caracanis*, *Toxascaris leonina*, *Uncinaria stenocephala*, *Ancylostoma caninum*

Cestodes: *Taenia hydatigena*, *Taenia pisiformis*, *Dipylidium caninum*

**5. CONTRAINDICATIONS**

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 or any other adverse reaction occurs, treatment with the product should be discontinued.

Do not use in dogs weighing less than 2 kg.



## 6. ADVERSE REACTIONS

**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

The dose of the product for the treatment of dogs is nitroscanate 50 mg/kg bodyweight, which is equivalent to 1 x 100 mg tablet per 2 kg (4.4 lb) of bodyweight.

Follow the dosage chart below:

<b>Dog's Weight</b>	<b>Example Breed</b>	<b>Number of Tablets</b>
Up to 2 kg (4.4 lb)	Chihuahua	One
2.1 - 4 kg (4.5 - 8.8 lb)	Miniature Dachshund	Two
4.1 - 6 kg (8.9 - 13.2 lb)	Miniature Poodle	Three
6.1 - 8 kg (13.3 - 17.6 lb)	West Highland Terrier	Four

For dogs weighing more than 8 kg (17.6 lb), use Beaphar One Dose Dog Wormer 500mg Nitroscanate Film-Coated Tablets.

## 9. ADVICE ON CORRECT ADMINISTRATION

Give the required number of tablets first thing in the morning when your dog's stomach is empty, with about one fifth of their daily food ration. The tablets should be given whole. Tablets are film coated and should not be broken or divided. Give your dog their remaining food in the evening, at least eight hours after the wormer dose.

## 10. WITHDRAWAL PERIOD

N/A

## 11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

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

Keep blister strips in outer carton.

Do not use after the expiry date stated on the label. The expiry date refers to the last day of that month.

## 12. SPECIAL WARNING(S)

- The product should not be administered to puppies less than 6 months old, owing to the need to restrict food intake at the time of administration.
- This product can be an irritant to the skin and eyes. Tablets are film-coated and should not be broken or divided.
- The product is not indicated for the treatment of *Trichuris vulpis*
- 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.
- If symptoms of disease persist or appear, consult your veterinary surgeon.
- Can be used safely during pregnancy and lactation.

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

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

## 14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

August 2022

## 15. OTHER INFORMATION

**Pack sizes:** 3, 4 and 6 tablets.  
100 tablets (for sale to veterinary surgeons only)

Not all pack sizes may be marketed.

**Distributor:** Beaphar UK Ltd., Rook Tree Farm, Withersfield Road, Great Wratting, Suffolk, CB9 7HD.

Vm: 11990/4009

Legal category:

AVM-GSL

**PACKAGE LEAFLET (for 100 tablet pack size only)**

Beaphar One Dose Small Dog Wormer 100mg Nitroscanate Film-Coated Tablets  
Beaphar One Dose Dog Wormer 500mg Nitroscanate Film-Coated Tablets

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

**M.A. Holder:** Chanelle Animal Health Ltd., 7 Rodney Street, Liverpool, L1 9HZ, UK.

**Manufacturer responsible for batch release:**

Chanelle Pharmaceuticals Manufacturing Ltd., Loughrea, Co. Galway, Ireland.  
Beaphar B.V., Oude Linderteseweg 9, 8102 EV Raalte, The Netherlands.  
Sinclair Animal and Household Care Limited, Ropery Road, Gainsborough, Lincolnshire, DN21 2QB, United Kingdom.

**2. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Beaphar One Dose Small Dog Wormer 100mg Nitroscanate Film-Coated Tablets  
Beaphar One Dose Dog Wormer 500mg Nitroscanate Film-Coated Tablets

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

Yellow coloured film-coated round convex tablets for oral administration. The products are available in two tablets strengths containing either 100 mg or 500 mg nitroscanate.

**4. INDICATION(S)**

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

**5. CONTRAINDICATIONS**

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 or any other adverse reaction occurs, treatment with the products should be discontinued.

Do not use in dogs weighing less than 2 kg.

## 6. ADVERSE REACTIONS

**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

Beaphar One Dose Small Dog Wormer 100mg Nitroscanate Film-Coated Tablets:  
For dogs.

Beaphar One Dose Dog Wormer 500mg Nitroscanate Film-Coated Tablets:  
For dogs.

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

**Dosage:** The dose of the product for the treatment of dogs is nitroscanate 50 mg/kg bodyweight, which is equivalent to 1 x 100 mg tablet per 2 kg (4.4 lb) bodyweight or 1 x 500 mg tablet per 10 kg (22 lb) bodyweight.

The advice of a veterinary surgeon should be sought regarding the need for and frequency of repeat treatment.

## 9. ADVICE ON CORRECT ADMINISTRATION

**Administration:** The tablet(s) should be administered orally in the morning after overnight fasting with approximately one-fifth of the daily food ration.

The remaining food ration should be withheld for at least 8 hours.

## 10. WITHDRAWAL PERIOD

N/A

## 11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

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

Do not use after the expiry date stated on the label. The expiry date refers to the last day of that month. Keep blister strips in outer carton.

## 12. SPECIAL WARNING(S)

The products can be an irritant to the skin and eyes. The tablets are film coated and therefore should not be broken or divided.

The product should not be administered to puppies less than 6 months old, owing to the need to restrict food intake at the time of administration.

Can be used safely during pregnancy and lactation.

### Further information:

i) The products are not indicated for the treatment of *Trichuris vulpis*

ii) 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.

iii) 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

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

## 14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

August 2022

## 15. OTHER INFORMATION

Pack sizes:

Beaphar One Dose Small Dog Wormer 100mg Nitroscanate Film-Coated Tablets;  
3, 4 and 6 tablets  
100 tablets (for sale to veterinary surgeons only)

Not all pack sizes may be marketed.

**Pack sizes:**

Beaphar One Dose Dog Wormer 500mg Nitroscanate Film-Coated Tablets;

1, 2 and 4 tablets

60 or 100 tablets (for sale to veterinary surgeons only)

Not all pack sizes may be marketed.

**Product Licence No.**

Beaphar One Dose Small Dog Wormer 100mg Nitroscanate Film-Coated Tablets:

Vm 11990/4009

Beaphar One Dose Dog Wormer 500mg Nitroscanate Film-Coated Tablets: Vm

11990/4010

**Distributor:** Beaphar UK Ltd., Rook Tree Farm, Withersfield Road, Great Wratting, Suffolk, CB9 7HD.

**Legal category**

AVM-GSL