<PARTICULARS TO APPEAR ON THE OUTER PACKAGE>

Carton

Beaphar One Dose Dog Wormer 500mg Nitroscanate Film-Coated Tablets 1 tablet, 2 tablets and 4 tablets only

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each tablet contains Nitroscanate 500mg

3. PHARMACEUTICAL FORM

Tablets

4. PACKAGE SIZE

- 1 tablet
- 2 tablets
- 4 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.

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

Repeat this treatment every three to six months as a preventative measure.

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.

8. WITHDRAWAL PERIOD

N/A

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

Contra-Indications:

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, cease treatment.

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

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.

10. EXPIRY DATE

<EXP >

11. SPECIAL STORAGE CONDITIONS

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

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

MA Holder: Chanelle Animal Health Ltd., 7 Rodney St., Liverpool L1 9HZ

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

16. MARKETING AUTHORISATION NUMBER

Vm 11990/4010

AVM-GSL

17. MANUFACTURER'S BATCH NUMBER

<BN>

<PARTICULARS TO APPEAR ON THE OUTER PACKAGE>

Carton

Beaphar One Dose Dog Wormer 500mg Nitroscanate Film-Coated Tablets 100 & 60 tablets only

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each tablet contains Nitroscanate 500mg

3. PHARMACEUTICAL FORM

Tablets

4. PACKAGE SIZE

60 tablets

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 500 mg tablet per 10 kg (22 lb) bodyweight.

Repeat this treatment every three to six months as a preventative measure.

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.

8. WITHDRAWAL PERIOD

N/A

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

Contra-Indications:

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, cease treatment.

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

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.

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

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

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

MA Holder: Chanelle Animal Health Ltd., 7 Rodney St., Liverpool L1 9HZ

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

16. MARKETING AUTHORISATION NUMBER

Vm 11990/4010

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 Dog Wormer 500mg Nitroscanate Film-Coated Tablets Nitroscanate 500mg 2. NAME OF THE MARKETING AUTHORISATION HOLDER Chanelle. 3. **EXPIRY DATE** <EXP > **BATCH NUMBER** <BN> THE WORDS "FOR ANIMAL TREATMENT ONLY" 5.

For animal treatment only.

PACKAGE LEAFLET (for 1, 2 and 4 tablet pack size only)

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 Dog Wormer 500mg Nitroscanate Film-Coated Tablets Nitroscanate

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

Each tablet contains Nitroscanate 500 mg.

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 product should be discontinued.

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 1 x 500 mg tablet per 10 kg (22 lb) of bodyweight. Repeat this treatment every three to six months as a preventative measure.

Follow the dosage chart below:

Dog's Weight		Example Breed	Number of Tablets
6-10 kg	(13.2-22lb)	West Highland Terrier	One
10.1 - 20 kg	(22.1 - 44 lb)	Springer Spaniel	Two
20.1 - 30 kg	(44.1 - 66 lb)	Labrador	Three

For dogs weighing over 30 kg (66 lb), give one additional tablet for every extra 10 kg (22 lb) in weight.

For smaller dogs weighing less than 6 kg use Beaphar One Dose Small Dog Wormer 100mg 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. 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 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.
- This product can be an irritant to the skin and eyes. Tablets are film-coated and 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.

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

Vm 11990/4010

Pack sizes: 1. 2 and 4 tablets

60 or 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.

Legal category AVM-GSL

PACKAGE LEAFLET (for 100 and 60 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 expiry date state 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 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.
- 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

Approved: 03 August 2022