

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

Carton
500mg

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Armitage Worm Away 500mg Film-Coated Tablets for Dogs
Nitroscanate

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each tablet contains nitroscanate 500mg

3. PHARMACEUTICAL FORM

Tablets

4. PACKAGE SIZE

1 tablet
4 tablets
60 tablets
100 tablets

5. TARGET SPECIES

Dogs

6. INDICATION(S)

The product is used for the treatment of the following tapeworms and intestinal roundworms:

Roundworms:

Ascarids: *Toxocara canis* (adult parasite stage), **Hookworms:** *Ancylostoma caninum* (adult parasite stage)

Tapeworms:

Taenia species (adult and immature parasite stages) and *Dipylidium caninum* (adult parasite stage).

7. METHOD AND ROUTE(S) OF ADMINISTRATION

READ THE ENCLOSED PACKAGE LEAFLET CAREFULLY BEFORE USE.

Dosage: The dose of the product is 50 mg nitroscanate/kg bodyweight, which is equivalent to 1 x 500 mg tablet per 10 kg (22 lb) bodyweight. Weigh the dog first and ensure the correct number of tablets is administered according to the weight of the dog.

The product should not be used in dogs weighing less than 10 kg.

For dogs weighing less than 10 kg (22.0 lb) use Armitage Worm Away 100 mg Film-Coated Tablets for Dogs, which are dosed at a rate of 1 x 100 mg tablet per 2 kg bodyweight.

To ensure precise dosing, Armitage Worm Away 100 and 500 mg Film-Coated Tablets for Dogs may be used in combination.

Directions for Use:

The product should be administered together with about one-fifth of the daily food ration in the morning when the dog's stomach is empty. Give the remaining food ration in the evening. Tablets are film coated and should not be broken or divided.

The advice of a veterinary surgeon, pharmacist or Suitably Qualified Person (SQP) should be sought regarding the need for and frequency of repeat treatment.

8. WITHDRAWAL PERIOD

N/A

9. SPECIAL WARNING(S), IF NECESSARY

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

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

Do not use if your dog is allergic to any of the ingredients.

. If an allergic reaction or any other adverse reaction occurs, cease treatment.

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

10. EXPIRY DATE

<EXP >

11. SPECIAL STORAGE CONDITIONS

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

UK authorised veterinary medicinal product.

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

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

16. MARKETING AUTHORISATION NUMBER(S)

Vm 08749/4075

NFA-VPS

17. MANUFACTURER’S BATCH NUMBER

<BN>

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

{NATURE/TYPE}
BLISTERS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Armitage Worm Away 500mg Film-Coated Tablets for Dogs
Nitroscanate

2. NAME OF THE MARKETING AUTHORISATION HOLDER

Chanelle Animal Health Ltd

3. EXPIRY DATE

<EXP >

4. BATCH NUMBER

<BN>

5. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

PACKAGE LEAFLET

Armitage Worm Away 500mg Film-Coated Tablets for Dogs
Nitroscanate

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

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

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Armitage Worm Away 500mg Film-Coated Tablets for Dogs
Nitroscanate

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

Each tablet contains Nitroscanate 500 mg.
Round convex tablets, yellow coloured, film coated.

4. INDICATION(S)

The product is used for the treatment of the following tapeworms (cestodes) and intestinal roundworms (nematodes):

Roundworms:

Ascarids: *Toxocara canis* (adult parasite stage)

Hookworms:

Ancylostoma caninum (adult parasite stage)

Tapeworms:

Taenia species (*T. hydatigena*, *T. pisiformis*, *T. ovis*) (adult and immature parasite stages) and *Dipylidium caninum* (adult parasite stage).

5. CONTRAINDICATIONS

Do not administer if your dog is sick or recovering from an illness.
Do not use if your dog is allergic to any of the ingredients.
Do not use if your dog weighs less than 10 kg.

6. ADVERSE REACTIONS

In rare cases, digestive disorders (excess salivation, vomiting, diarrhoea, blood in vomit or diarrhoea) can occur after administration of the product. Do not repeat treatment if vomiting occurs shortly after dosing.

Neurological disorders such as convulsions/epileptic seizures, muscle incoordination (ataxia), trembling (muscle tremors) and collapse may occur in very rare cases following administration of the product.

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

- very common (more than 1 in 10 animals treated displaying adverse reactions)
- 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 is 1 x 500 mg tablet per 10 kg (22 lb) bodyweight.

Weigh the dog first and ensure the correct number of tablets are administered according to the weight of the dog.

The product should not be used in dogs weighing less than 10 kg. For smaller dogs weighing less than 10 kg use Armitage Worm Away 100 mg Film-coated Tablets for Dogs, which are dosed at a rate of 1 x 100 mg tablet per 2 kg bodyweight.

To ensure precise dosing, Armitage Worm Away 100 and 500 mg Film-Coated Tablets for Dogs may be used in combination.

9. ADVICE ON CORRECT ADMINISTRATION

The product should be administered together with about one-fifth of the daily food ration in the morning when the dog's stomach is empty. Give the remaining food ration in the evening. The tablets should be given whole.

10. WITHDRAWAL PERIOD

None

11. SPECIAL STORAGE PRECAUTIONS

Keep out of 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. Keep blister strip in outer carton.

12. SPECIAL WARNING(S)

Special warnings for each target species:

Since the most common tapeworm of the dog (*Dipylidium caninum*) is transmitted by a flea and has a very short pre-patent period (life cycle), it is important to pay attention to flea control to reduce the risk of tapeworm in your dog.

The advice of a veterinary surgeon, pharmacist or Suitably Qualified Person (SQP) should be sought regarding the need for and frequency of repeat treatment.

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

Special precautions for use in animals:

Do not use in puppies less than 6 months old because of the need to restrict food intake at the time of administration. See also 'Advice on correct administration'.

If your dog has an allergic reaction to the product then do not administer it again.

Special precautions to be taken by the person administering the veterinary medicinal product to animals.

Tablets are film-coated and should not be broken or divided to avoid skin and eye irritation.

This product may cause hypersensitivity (allergy). Avoid contact with this product if you know you are sensitised.

Accidental ingestion may cause gastro-intestinal disturbances. If symptoms persist, seek medical advice and show the package leaflet or the label to the physician.

Wash hands after use.

Use during pregnancy and lactation

The product can be safely used in pregnant and lactating bitches.

Interaction with other medicinal products and other forms of interaction

None known.

Overdose

See 'Adverse reactions' section. Adverse events are more likely to occur if the product is overdosed.

In a safety study, elevated levels of the liver enzymes alanine transferase (ALT), amylase and alkaline phosphatase (ALKP), indicative of liver disease, were observed in dogs administered the product at 5-8 times the recommended dose.

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.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

15. OTHER INFORMATION

Vm 08749/4075

Contents:

One tablet, four tablets, 60 tablets or 100 tablets

Legal category

NFA-VPS

Approved: 22 March 2019

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