LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE
{Carton}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

RidaWorm 100mg Film-Coated Tablets for Dogs
Nitroscanate

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each tablet contains Nitroscanate 100 mg.

3. PHARMACEUTICAL FORM

Tablets

4. PACKAGE SIZE

4 tablets
6 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 100 mg tablet per 2 kg (4.4 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 2 kg.**
RidaWorm 500 mg Film-Coated Tablets for Dogs can be used in dogs weighing more than 10 kg (22 lb).

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. This product can be an irritant to the skin and eyes.
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

Store in a dry place. Do not store above 25°C. Do not use after expiry date stated on the label.
Keep blister strip in outer carton.

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

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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.

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)

Legal category
NFA-VPS
Vm 08749/4072

17. MANUFACTURER'S BATCH NUMBER

<BN>

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

{NATURE/TYPE}
BLISTERS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

RidaWorm 100mg Film-Coated Tablets for Dogs
Nitroscanate

2. NAME OF THE MARKETING AUTHORISATION HOLDER

Chanelle Pharmaceuticals Manufacturing Limited

3. EXPIRY DATE

<EXP >

4. BATCH NUMBER

<BN>

5. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

PACKAGE LEAFLET

RidaWorm 100mg Film-Coated Tablets for Dogs

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

RidaWorm 100mg Film-Coated Tablets for Dogs
Nitroscanate

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

Each tablet contains Nitroscanate 100 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 stages)
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 2 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 100 mg tablet per 2 kg (4.4 lb) of 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 2 kg. RidaWorm 500 mg Film-Coated Tablets for Dogs can be used in dogs weighing more than 10 kg (22 lb).

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

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 strip in outer carton
Do not use this veterinary medicinal product after the expiry date which is stated on the 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

Pack sizes for this product: 4 tablets, 6 tablets, 100 tablets

Vm: 08749/4072
Legal category: NFA-VPS

Approved: 30 May 2019