SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

RidaWorm 500mg Film-Coated Tablets for Dogs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains

Active substances:
Nitroscanate 500 mg

Excipient(s):
Titanium Dioxide (E171) 3.950 mg
Ferric Oxide Yellow (E172) 0.1306 mg
Ferric Oxide Black (E172) 0.00013 mg
Ferric Oxide Red (E172) 0.00013 mg
As constituents of Opadry OY-GM 7900

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Film-coated tablet.
Round convex tablets, yellow coloured, film coated.

4. CLINICAL PARTICULARS

4.1 Target species

Dogs.

4.2 Indications for use, specifying the target species

Treatment of the following cestodes (tapeworms) and intestinal nematodes (roundworms):
Nematodes:
Ascarids: *Toxocara canis* (adult parasite stage)
Hookworms:
Ancylostoma caninum (adult parasite stages)
Cestodes
Taenia species (*T. hydatigena, T. pisiformis*, *T.* ovis) (adult and immature parasite stages) and *Dipylidium caninum* (adult parasite stage).

4.3 Contraindications

Do not administer to dogs that are sick or recovering from an illness.
Do not use in known cases of hypersensitivity to the active substance or to any of the excipients.
Do not use in dogs weighing less than 10 kg.

4.4 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, it is important to pay attention to flea control to reduce the incidence of tapeworm in the animal.
The advice of a veterinary surgeon, pharmacist or Suitably Qualified Person (SQP) should be sought regarding the need for and frequency of repeat treatment.

4.5 Special precautions for use

i Special precautions for use in animals
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. See also section 4.9.
If a hypersensitivity reaction occurs treatment should be discontinued.

ii 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.

4.6 Adverse reactions (frequency and seriousness)

In rare cases, digestive tract disorders (hypersalivation, vomiting, diarrhoea, blood in vomit or diarrhoea) have been reported. Do not repeat treatment if vomiting occurs shortly after dosing. Treat symptomatically.
Neurological disorders (convulsions/epileptic seizures, ataxia, muscle tremors and collapse) may occur in very rare cases.
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).

4.7 Use during pregnancy, lactation or lay

The product can be safely used during pregnancy and lactation.

4.8 Interaction with other medicinal products and other forms of interaction

None known

4.9 Amounts to be administered and administration route

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. To ensure precise dosing, the product may be used in combination with RidaWorm 100 mg Film-Coated Tablets for Dogs, which are dosed at a rate of 1 x 100 mg tablet per 2 kg bodyweight.

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.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

See section 4.6. Adverse events are more likely to occur if the product is overdosed.

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

4.11 Withdrawal period

Not applicable

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Anthelmintic, Other anthelmintic agents, nitroscanate
ATCvet Code: QP52AX01

5.1 Pharmacodynamic Properties

The mode of action of nitroscanate has not been well established. However, there is some evidence that nitroscanate decreases the ATP/ADP ratio affecting energy producing pathways within the target parasites. This leads to the death of the parasite. The concentration of unabsorbed nitroscanate in contact with the helminths appears to be more important for efficacy than absorption into the blood.

5.2 Pharmacokinetic Properties

Pharmacokinetic data from dogs are not available. In other species (mice and sheep), the drug is only partly absorbed from the gastrointestinal tract when administered orally, with the majority of the dose being eliminated in the faeces. The remainder of the dose is metabolised and excreted in the urine.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Opadry-Oy-GM 7900, consisting of:
- Titanium Dioxide (E171)
- Ferric Oxide Yellow (E172)
- Ferric Oxide Black (E172)
- Ferric Oxide Red (E172)

Sodium Starch Glycolate
Maize Starch
Cellulose, Microcrystalline
Sodium Laurilsulfate
Magnesium Stearate

6.2 Incompatibilities

None known

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 5 years

6.4 Special precautions for storage

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

6.5 Nature and composition of immediate packaging

Aluminium foil, low density polyethylene strips in outer carton containing
1 x 1 tablet
1 x 4 tablets
1x 60 tablets
1 x 100 tablets

Not all pack sizes may be marketed

6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products, if appropriate

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

Chanelle Pharmaceutical Manufacturing Ltd.
Loughrea
Co. Galway
Ireland

8. MARKETING AUTHORISATION NUMBER

Vm 08749/4073

9. DATE OF FIRST AUTHORISATION

30 May 2019

10. DATE OF REVISION OF THE TEXT

May 2019

Approved: 30 May 2019