

## **SUMMARY OF PRODUCT CHARACTERISTICS**

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

Armitage Worm Away 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 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.

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 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 08749/4075

**9. DATE OF FIRST AUTHORISATION**

22 March 2019

**10. DATE OF REVISION OF THE TEXT**

March 2019

Approved: 22 March 2019

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