

## **SUMMARY OF PRODUCT CHARACTERISTICS**

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

Pets with Wilko One Dose Worming Tablets for Small Dogs and Puppies, 100 mg film-coated tablets

### **2. QUALITATIVE AND QUANTITATIVE COMPOSITION**

<u>Active substance</u>	<u>mg/tablet</u>
Nitroscanate	100

<u>Other ingredients</u>	
Titanium Dioxide (E171)	0.778
Ferric Oxide Yellow (E172)	0.0257
Ferric Oxide Black (E172)	0.00003
Ferric Oxide Red (E172)	0.00003

For full list of excipients, see section 6.1.

### **3. PHARMACEUTICAL FORM**

Film-coated tablets

Round, convex, yellow coloured film coated tablets. Diameter 7.0 mm  $\pm$  0.15 mm.

### **4. CLINICAL PARTICULARS**

#### **4.1 Target species**

Dogs

#### **4.2 Indications for use, specifying the target species**

For the treatment the following nematodes (roundworms) and cestodes (tapeworms): Nematodes: *Toxocara canis*, *Toxascaris leonina*, *Uncinaria stenocephala*, *Ancylostoma caninum*. Cestodes: *Taenia hydatigena*, *Taenia pisiformis*, and *Dipylidium caninum*.

#### **4.3 Contra-indications**

Do not use in dogs weighing less than 2 kg.

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 reaction occurs treatment should be discontinued.

#### **4.4 Special warnings for each target species**

It is recommended that adult dogs should be wormed routinely 2 – 4 times a year. 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.

It is important to worm young puppies very regularly for roundworm with a suitable product. Pets with Wilko One Dose Worming Tablets for Small Dogs and Puppies can be used at 12, 16 and 24 weeks of age. An alternative worming product must be used in younger puppies. Nursing bitches should be treated at the same time and as frequently as puppies up to 12 weeks of age. Thereafter the adult worming regime of 2 –4 times a year is recommended.

#### **4.5 Special precautions for use**

##### **(i) Special precautions for use in animals**

The product should not be administered to puppies less than 12 weeks old owing to the need to restrict food intake at the time of administration. See also section 4.9.

##### **(ii) Special precautions to be taken by the person administering the medicinal product to animals**

This product can be an irritant to the skin and eyes.  
Tablets are film-coated and should not be broken or divided.  
Wash hands after use.

#### **4.6 Adverse reactions (frequency and seriousness)**

During the post-marketing surveillance, 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).

#### **4.7 Use during pregnancy, lactation or lay**

Can be used safely 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**

**Dose:** For treatment of roundworm and tapeworm in small dogs and puppies give 1 x 100mg tablet per 2kg (4.4lb) bodyweight, equivalent to 50mg nitroscanate/kg bodyweight.

For dogs weighing more than 8kg (17.5lb) use Wilko One Dose Worming Tablets for Dogs, 500 mg Film-coated Tablets.

**Directions for use:** The product should be administered orally in the morning after overnight fasting with approximately one-fifth of the daily food ration. To reduce the risk of vomiting, it is recommended that the remaining food ration is withheld for at least 8 hours afterwards.

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

No information – treatment should be symptomatic.

#### **4.11 Withdrawal period(s)**

Not applicable.

### **5. PHARMACOLOGICAL PROPERTIES**

Pharmacotherapeutic group: Anthelmintics, 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 particulars**

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**

Titanium Dioxide (E171)  
Ferric Oxide Yellow (E172)  
Ferric Oxide Black (E172)  
Ferric Oxide Red (E172)

Maize Starch  
Microcrystalline Cellulose  
Sodium Starch Glycollate  
Sodium Lauryl Sulphate  
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

### **6.5 Nature and composition of immediate packaging**

Aluminium foil, low density polyethylene strips in outer carton or  
Aluminium Foil blisters comprising:  
Hard tempered aluminium lidding foil and cold formable aluminium bottom foil in  
outer carton.

Cartons containing three tablets.

### **6.6 Special precautions for the disposal of unused veterinary medicinal products 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 products should be disposed of in accordance with local  
requirements.

**7. MARKETING AUTHORISATION HOLDER**

Sinclair Animal and Household Care Ltd  
Ropery Road  
Gainsborough  
Lincolnshire  
DN21 2QB

**8. MARKETING AUTHORISATION NUMBER**

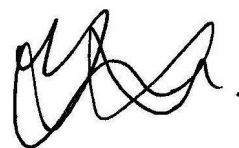
Vm 16516/4013

**9. DATE OF FIRST AUTHORISATION**

7 March 2001

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

December 2022

A handwritten signature in black ink, consisting of several loops and a final horizontal stroke.

Approved: 20 December 2022