SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Johnson's One Dose Wormer for Dogs 500mg film-coated tablets

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains:

Active substance:	**mg**
Nitroscanate	500
Excipients:	
Titanium Dioxide (E171)	3.95
Iron Oxide Yellow (E172)	0.1306
Iron Oxide Black (E172)	0.00013
Iron Oxide Red (E172)	0.00013

For the full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Film coated tablet.
Smooth yellow coloured film coated tablets, convex shaped (plain round concave).

4. CLINICAL PARTICULARS

4.1 Target species

Dog.

4.2 Indications for use, specifying the target species

For the treatment of 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 Contraindications

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. Johnson's One Dose Wormer for Small Dogs and Puppies 100 mg Film-Coated Tablets 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 2, 4, 6, 8 and 12 weeks after whelping. Thereafter the adult worming regime of 2 - 4 times a year is recommended.
If symptoms of disease persist or appear, consult your veterinary surgeon.

4.5 Special precautions for use

Special precautions for use in animals
Is irritant, tablets should not be broken. 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.

Special precautions to be taken by the person administering the veterinary 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.

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 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 for the treatment of adult dogs is nitroscanate 50mg/kg bodyweight, which is equivalent to 1 x 500 mg tablet per 10 kg (22 lb) bodyweight.

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 8 hours afterwards.

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

No treatment specified.

4.11 Withdrawal period(s)

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 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)
Iron Oxide Yellow (E172)
Iron Oxide Black (E172)
Iron Oxide Red (E172)
Maize starch
Sodium starch glycolate (Type A)
Microcrystalline cellulose (E460)
Sodium laurel sulfate
Magnesium stearate (E572)
HPMC 2910
Polydextrose FCC
Macrogol 4000

6.2 Major incompatibilities

Not applicable.

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 strips, low density polyethylene strip packs with heat sealed closure containing 2, 3, 4 or 8 x 500 mg tablets in a cardboard box.

Blister foil made up of a hard tempered aluminium lidding foil and a cold formable PA/Alu/PVC film, containing 2, 3, 4 or 8 x 500 mg tablets in a cardboard box.

Not all pack sizes will be marketed.

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

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

Chanelle Animal Health Ltd
7 Rodney Street
Liverpool
L1 9HZ

8. MARKETING AUTHORISATION NUMBER

Vm 11990/4028

9. DATE OF FIRST AUTHORISATION

15 April 2002

10. DATE OF REVISION OF THE TEXT

December 2021

Approved 29 December 2021