

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Johnson's One Dose Easy Wormer for Dogs and Puppies, 500mg film coated tablets

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

<u>Active ingredient</u>	<u>mg/tablet</u>
Nitroscanate	500

For a full list of excipients see section 6.1.

3. PHARMACEUTICAL FORM

Film coated tablet.

Yellowish-white to light beige round, film coated tablet, with imprint 1. BCB and imprint 2. CGV.

4. CLINICAL PARTICULARS

4.1 Target Species

Dogs.

4.2 Indications for use, specifying the target species

Nitroscanate is a broad spectrum anthelmintic for use in dogs. It is highly effective in a single dose against common canine nematodes and cestodes in the UK: *Toxocara canis*, *Toxascaris leonina*, *Ancylostoma caninum*, *Uncinaria stenocephala*, *Taenia ovis*, *Taenia hydatigena*, *Taenia pisiformis* and *Dipylidium caninum*.

At the recommended dosage, the product gives limited control of *Echinococcus granulosus*.

4.3 Contraindications

None.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

i) Special precautions for use in animals

Do not repeat treatment if vomiting occurs shortly after dosing.

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

Tablets are film coated and should not be broken or divided.

4.6 Adverse reactions (frequency and seriousness)

The tablets, when administered as recommended are unlikely to cause vomiting. Do not repeat treatment if vomiting occurs shortly after dosing.

4.7 Use during pregnancy, lactation or lay

Not contraindicated in pregnant animals. Nursing bitches should be treated at the same time and as frequently as puppies up to 12 weeks of age (i.e. 2, 4, 6, 8, 12 weeks).

4.8 Interaction with other medicinal products and other forms of interaction

None known.

4.9 Amount(s) to be administered and administration route

For the routine treatment of puppies and adult dogs, the dose of the product is 50 mg/kg (1 x 500 mg tablet per 10 kg/22 lb bodyweight).

Practical dosage regime: 500 mg tablets.

Bodyweight	Number of Tablets
6.1 – 10 kg	1 x 500 mg
10.1 – 20 kg	2 x 500 mg
20.1 – 30 kg	3 x 500 mg
30.1 – 40 kg	4 x 500 mg

For larger dogs, weighing more than 40 kg, give one additional tablet for every 10 kg increase in bodyweight.

For best results give the product 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 and antidotes), if necessary

Overdose may cause nausea and vomiting. High doses may have CNS effects. Treat symptomatically.

4.11 Withdrawal period(s)

Not applicable.

5. PHARMACOLOGICAL PROPERTIES

Broad spectrum anthelmintic.
ATC code: QP52AX01

5.1 Pharmacodynamic properties

Nitroscanate is a broad spectrum anthelmintic for use in small animals against Toxocara, Taenia, Dipylidium, Ancylostoma, Uncinaria and partially against Echinococcus.

5.2 Pharmacokinetic particulars

No current information is available.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Methylcellulose
Silica Colloidal Anhydrous
Maize starch
Cellulose Microcrystalline
Magnesium Stearate
Hypromellose
Macrogol 8000
Purified talc

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

Pack size: 2, 4, or 8 tablets.
Container: Polyethylene-coated aluminium foil strip-pack.
Not all pack sizes may be marketed.

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 material derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

Elanco Europe Ltd
Form 2, Bartley Way
Bartley Wood Business Park
Hook
RG27 9XA
United Kingdom

8. MARKETING AUTHORISATION NUMBER

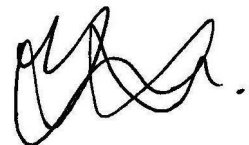
Vm 00879/4064

9. DATE OF FIRST AUTHORISATION

26 January 1998

10. DATE OF REVISION OF THE TEXT

October 2020

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

Approved: 22 October 2020