

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Beaphar One Dose Wormer for Dogs, 500 mg 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 'BCB' imprinted on one side and 'CGV' on the other.

4. CLINICAL PARTICULARS

4.1 Target Species

Dogs.

4.2 Indications for use, specifying the target species

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 oral administration only. For the routine treatment of 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 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

Anthelmintic.

ATC code: QP52AX01

5.1 Pharmacodynamic properties

Nitroscanate is a broad spectrum anthelmintic.

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, 3, 4, 6 or 100 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
Lilly House
Priestley Road
Basingstoke
Hampshire
RG24 9NL

8. MARKETING AUTHORISATION NUMBER

Vm 00879/4056

9. DATE OF FIRST AUTHORISATION

30 June 2000

10. DATE OF REVISION OF THE TEXT

November 2018

A handwritten signature in black ink, appearing to be 'H. Lilly', with a long horizontal stroke extending to the right.

Approved 01 November 2018