

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Beaphar Easy One Dose Wormer for Medium and Large Dogs, 500 mg Film-Coated Tablets

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

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

<u>Other ingredients</u>	
Titanium Dioxide (E171)	3.95
Ferric Oxide Yellow (E172)	0.1306
Ferric Oxide Black (E172)	0.00013
Ferric Oxide Red (E172)	0.00013

For full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Film-coated tablets

Round, convex, yellow coloured film coated tablets. Diameter 12.0 mm \pm 0.25 mm

4. CLINICAL PARTICULARS

4.1 Target species

Dogs

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 Contra-indications

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. 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

(i) Special precautions for use in animals

The product 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.

(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

Puppies (up to 24 weeks) and small dogs less than 8 kg (17.5 lb): use Beaphar Easy One Dose Worming Tablets for Small Dogs & Puppies, 100mg film-coated tablets.

The dose for the routine treatment of adult dogs is Nitroscanate 50 mg/kg bodyweight, which is equivalent to 1 x 500 mg tablet per 10 kg (22 lb) bodyweight. Beaphar Easy One Dose Worming Tablets for Dogs 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 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)
Sodium Starch Glycollate
Maize Starch
Microcrystalline Cellulose
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 two 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 16516/4006

9. DATE OF FIRST AUTHORISATION

02 March 2001

10. DATE OF REVISION OF THE TEXT

May 2024

Gavin Hall
Approved: 15 May 2024