SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Beaphar One Dose Dog Wormer 500 mg Nitroscanate Film-Coated Tablets

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substances:
Nitroscanate 500 mg

Excipient(s):
Titanium Dioxide (E171) 0.8038 mg
Ferric Oxide Yellow (E172) 0.0257 mg
Ferric Oxide Black (E172) 0.00003 mg
Ferric Oxide Red (E172) 0.00003 mg
As constituents of Opadry OY-GM 7900

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Film-coated tablet.
Round convex tablets, yellow coloured, film coated.

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*, Un*cinaria stenocephala*, *Ancylostoma caninum*

Cestodes: *Taenia hydatigena*, *Taenia pisiformis*, *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

Is not indicated for the treatment of *Trichuris vulpis.* 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.
If symptoms of disease persist or appear, consult your veterinary surgeon.

4.5 Special precautions for use

i **Special precautions for use in animals**
As this product may be irritant, tablets should not be broken.
The product should not be administered to puppies less than 6 months 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 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)

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 dogs is nitroscanate 50mg/kg bodyweight, which is equivalent to 1 x 500 mg tablet per 10 kg (22 lb) bodyweight. Adult dogs should be dosed 2 – 4 times a year.
Should be administered orally in the morning after overnight fasting with approximately one-fifth of the daily food ration. The remaining food ration should be withheld for at least 8 hours.

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

See section 4.6. Adverse events are more likely to occur if the product is overdosed.

4.11 Withdrawal period

Not applicable

5. PHARMACOLOGICAL PROPERTIES AND PHARMACOKINETIC PARTICULARS

Pharmacotherapeutic group: Anthelmintic
ATCvet Code QP52AX01

Nitroscanate is a broad spectrum anthelmintic effective against gastrointestinal nematodes and cestodes.

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 Properties

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

Opadry-Oy-GM 7900, consisting of:
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 Major 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

Cartons containing
100 tablets or 60 tablets (for sale to veterinary surgeons only)
1 x 1 for OTC sale
1 x 2 for OTC sale
1 x 4 for OTC sale

Not all pack sizes may be marketed.

6.6 Special precautions for the disposal of unused veterinary medicinal product 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 product 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 11990/4010

9. DATE OF FIRST AUTHORISATION

27 January 1994

10. DATE OF REVISION OF THE TEXT

February 2022

Approved 17 February 2022