

Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Troscan 500 mg film coated tablet for Dogs

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains:

Active substances:

Nitroscanate	500	mg
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Excipients:

Titanium Dioxide (E171)	3.950	mg
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Iron Oxide Yellow (E172)	0.1306	mg
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Iron Oxide Black (E172)	0.00013	mg
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Iron Oxide Red (E172)	0.00013	mg
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For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Film coated tablet.

Yellow film coated round convex tablet.

4 CLINICAL PARTICULARS

4.1 Target Species

Dogs

4.2 Indications for use, specifying the target species

The product is a broad spectrum anthelmintic for use in puppies and adult dogs for the treatment of infection by adult intestinal nematodes or cestodes of the following species:

Nematodes: *Toxocara canis*, *Toxascaris leonina*, *Ancylostoma caninum*, *Uncinaria stenocephala*

Cestodes: *Taenia hydatigena*, *Taenia pisiformis*, *Dipylidium caninum*

4.3 Contraindications

Do not administer to sick or convalescing animals. Do not use in puppies of less than 3 weeks of age.

Do not use in cases of hepatic dysfunction. Do not use in cases of known hypersensitivity to the active substance.

4.4 Special warnings for each target species

The product is not indicated for the treatment of *Trichuris vulpis* and gives only a limited level of control of *Echinococcus granulosus*.

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 the animal.

4.5 Special precautions for use

Special precautions for use in animals

Do not repeat treatment if vomiting occurs shortly after dosing

In order to minimize the risk of vomiting, administer with food (see section 4.9)

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

Wash hands after use.

4.6 Adverse reactions (frequency and seriousness)

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 treated)
- Uncommon (more than 1 but less than 10 animals in 1,000 treated)
- Rare (more than 1 but less than 10 animals in 10,000 treated)
- Very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

When the product is not administered as recommended vomiting or mild diarrhoea may occur very rarely.

4.7 Use during pregnancy, lactation or lay

The product can be used during pregnancy and lactation.

4.8 Interaction with other medicinal products and other forms of interactions

None known

4.9 Amounts to be administered and administration route

For oral administration.

The dose is 50 mg nitroscanate per kg bodyweight, which is equivalent to 1 x 500 mg tablet per 10 kg bodyweight.

Tablets should not be broken before administration.

The dosing program should be established by the veterinary surgeon.

The product 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

In studies using up to nine times the recommended dose of nitroscanate dogs showed no clinical symptoms. However, increased levels of serum enzymes ALT and ALP suggestive of liver dyscrasia were observed in some of the dogs receiving 3 (for ALT) or 5 (for ALT and ALP) times the recommended dose.

4.11 Withdrawal period(s)

Not applicable

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Active Substance: Nitroscanate

Pharmacotherapeutic group: Anthelmintic.

ATCvet-code: QP52AX01

5.1 Pharmacodynamic properties

Nitroscanate is an anthelmintic of the diphenyloxide group. Nitroscanate is known to interfere with and inhibit the synthesis of ATP in *Fasciola hepatica* while A.M.P. levels are increased. The alterations in A.T.P. levels are shown to be irreversible and continuous with time. Neither interference in the uptake of glucose nor the mobilisation of glycogen are observed. An initial increase in end-product formation, namely acetate and lactate is observed, possibly due to increased levels of the enzyme phosphofructokinase resulting from depletion of A.T.P. levels, but this increase is later abolished. In the nematode *Haemonchus contortus* adenine nucleotide pools are depressed by nitroscanate.

Efficacy of nitroscanate is increased approximately four-fold if given with food due to slower passage of the drug through the gastrointestinal tract, with increased contact time with the parasite.

5.2 Pharmacokinetic particulars

When administered orally, the drug is only partly absorbed from the gastrointestinal tract, with the majority of the dose being eliminated in the faeces. The remainder of the dose is metabolised and excreted in the urine. The principal urinary metabolite is

4-(4-aminophenoxy) acetanilide. The concentration of nitroscanate in contact with the helminths in the gastrointestinal tract and the absorption into the fatty layers of these helminths is probably more important for the purpose of efficacy than absorption into the blood.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Maize starch
Sodium starch glycolate (Type A)
Microcrystalline cellulose (E460)
Sodium laurel sulphate
Magnesium stearate (E572)
HPMC 2910
Polydextrose FCC
Polyethylene glycol 4000
Titanium Dioxide (E171)
Iron Oxide Yellow (E172)
Iron Oxide Black (E172)
Iron Oxide Red (E172)

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.

6.5 Nature and composition of immediate packaging

1. Aluminium foil strips in outer carton.
or
2. Aluminium foil blister containing:
 - Lidding foil: 20 micron hard tempered aluminium foil - one side coated with heatseal lacquer and one side primed for printing.
 - Blister film: Cold formable Aluminium Bottom foil oPA/Alu/PVC - 25/45/60 micron.

100 tablets and 60 tablets (for veterinary surgeons only)
1 x 4 tablets

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

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 Pharmaceuticals Manufacturing Limited
Loughrea
Co. Galway
21 June 2019

Ireland

8 MARKETING AUTHORISATION NUMBER(S)

VPA10987/141/002

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 01 October 1988

Date of last renewal: 18 April 2019

10 DATE OF REVISION OF THE TEXT

June 2019