1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Troscan 100 mg film coated tablet for Dogs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains:

Active substance:
Nitroscanate 100 mg

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Titanium Dioxide (E171)	0.778 mg
Iron Oxide Yellow (E172)	0.0257 mg
Iron Oxide Black (E172)	0.00003 mg
Iron Oxide Red (E172	0.00003 mg
Maize starch	
Sodium starch glycolate (Type A)	
Microcrystalline cellulose (E460)	
Sodium laurel sulphate	
Magnesium stearate (E572)	
HPMC 2910	
Polydextrose FCC	
Polyethylene Glycol 4000	

Yellow film coated round convex tablet.

3. CLINICAL INFORMATION

3.1 Target species

Dogs.

3.2 Indications for use for each target species

The veterinary medicinal 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.*

3.3 Contraindications

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

Do not use in cases of hypersensitivity to the active substance or to any of the excipients.

3.4 Special warnings

The veterinary medicinal 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.

3.5 Special precautions for use

Special precautions for safe use in the target species:

Do not repeat treatment if vomiting occurs shortly after dosing.
In order to minimise the risk of vomiting, administer with food (See section 3.9).

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
Wash hands after use.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Dogs:

Very rare (<1 animal / 10 000 animals treated, including isolated reports):	Vomiting[1], diarrhoea[1,2]

[1]May occur when the product is not administered as recommended.
[2]Mild

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy and lactation:

Can be used during pregnancy and lactation.

3.8 Interaction with other medicinal products and other forms of interaction

None known.

3.9 Administration routes and dosage

For oral use.

The dose is 50 mg nitroscanate per kg bodyweight, which is equivalent to 1 x 100 mg tablet per 2 kg bodyweight. Tablets should not be broken before administration.
The dosing program should be established by the veterinary surgeon.

Dosing Guide:

Dogs Weight	Example Breed (adult weight)	No. of Tablets
2.1 - 4 kg	Miniature	2
4.1 - 6 kg	Dachshund	3
6.1 - 8 kg	Miniature Poodle West Highland Terrier	4

For dogs weighing more than 8 kg, use the 500 mg film coated tablet for adult dogs.

The veterinary medicinal 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.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

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.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 Withdrawal periods

Not applicable.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code :

QP52AX01

4.2 Pharmacodynamics

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.

4.3 Pharmacokinetics

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.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Not applicable.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 5 years.

5.3 Special precautions for storage

Store in a dry place.
Do not store above 25 °C.

5.4 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 (for veterinary surgeons only)
1 x 6 tablets
1 x 4 tablets
Not all pack sizes may be marketed.

5.5 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products

Medicines should not be disposed of via wastewater or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Chanelle Pharmaceuticals Manufacturing Limited

7. MARKETING AUTHORISATION NUMBER(S)

VPA10987/141/001

8. DATE OF FIRST AUTHORISATION

10/02/1994

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

17/07/2025

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product not subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).