1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Troscan 500 mg film coated tablet for Dogs. (IE)
VermiScan Clément Thékan Chiens 500 mg (FR)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains:

Active substance:

Nitroscanate 500 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)	3.950 mg
Iron Oxide Yellow (E172)	0.1306 mg
Iron Oxide Black (E172)	0.00013 mg
Iron Oxide Red (E172)	0.00013 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 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 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 500 mg tablet per 10 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
8 - 10 kg	Scottish Terrier	1
10.1 – 20 Kg	Springer Spaniel	2
20.1 – 30 Kg	Labrador	3
30.1 – 40 Kg	German Shepherd	4

For dogs weighing over 40 kg additional packs will be required. Give an additional tablet for every extra 10 kg in weight. For dogs weighing less than 8 kg use nitroscanate 100 mg tablet.

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> <IMMUNOLOGICAL> 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 and 60 tablets (for veterinary surgeons only).
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 Ltd.

7. MARKETING AUTHORISATION NUMBER(S)

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: {DD/MM/YYYY}

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

{MM/YYYY}

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).

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Carton

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Troscan 500 mg film coated tablet

2. STATEMENT OF ACTIVE SUBSTANCES

Active substances:
Nitroscanate 500 mg

3. PACKAGE SIZE

4 tablets
60 tablets
100 tablets

4. TARGET SPECIES

Dogs.

5. INDICATIONS

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.*

6. ROUTES OF ADMINISTRATION

For oral use.
The dose for the treatment of adult dogs is 1 x 500 mg tablet per 10 kg bodyweight.
The dosing program should be established by the veterinary surgeon.

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp. {mm/yyyy}

9. SPECIAL STORAGE PRECAUTIONS

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

10. THE WORDS "READ THE PACKAGE LEAFLET BEFORE USE"

Read the package leaflet before use.

11. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

12. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

Chanelle Pharmaceuticals Manufacturing Ltd.

14. MARKETING AUTHORISATION NUMBERS

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Blister or strip

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Troscan 

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Nitroscanate 500 mg

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Troscan 500 mg film coated tablet for Dogs (IE)
VermiScan Clément Thékan Chiens 500 mg (FR)

2. Composition

Each tablet contains:

Active substance:	
Nitroscanate	500 mg
Excipients:	
Titanium Dioxide (E171)	3.950 mg
Iron Oxide Yellow (E172)	0.1306 mg
Iron Oxide Black (E172)	0.00013 mg
Iron Oxide Red (E172)	0.00013 mg

Yellow film coated round convex tablet.

3. Target species

Dogs  .

4. Indications for use

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.*

5. 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 hypersensitivity to the active substance or to any of the excipients.

6. Special warnings

Special warnings:
Administer with food.
Do not repeat treatment if vomiting occurs shortly after dosing.

Special precautions for safe use in the target species:
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 your pet.

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

Pregnancy and lactation:
Can be used during pregnancy and lactation.

Overdose:
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.

7. 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 product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder <or its local representative> using the contact details at the end of this leaflet, or via your national reporting system: {national system details}

8. Dosage for each species, routes and method of administration

For oral use.
The dose of the 500 mg film coated tablet for the treatment of adult dogs is nitroscanate 50 mg/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 with the veterinary surgeon.

Dosage Guide:

Dogs Weight	Example Breed (adult weight)	No. of Tablets
8 - 10 kg	Scottish Terrier	1
10.1 – 20 Kg	Springer Spaniel	2
20.1 – 30 Kg	Labrador	3
30.1 – 40 Kg	German Shepherd	4

For dogs weighing over 40 kg additional packs will be required. Give an additional tablet for every extra 10 kg in weight. For dogs weighing less than 8 kg use nitroscanate 100 mg tablet.

9. Advice on correct administration

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.

10. Withdrawal periods

Not applicable.

11. Special storage precautions

Keep out of the sight and reach of children.
Store in a dry place.
Do not store above 25°C.
Do not use this veterinary medicinal product after the expiry date which is stated on the carton. The expiry date refers to the last day of that month.

12. Special precautions for disposal

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 applicable national collection systems. These measures should help to protect the environment.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product not subject to prescription.

14. Marketing authorisation numbers and pack sizes

Pack sizes: 4, 60, 100 tablets.
Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

{MM/YYYY}

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

16. Contact details

Marketing authorisation holder and manufacturer responsible for batch release :

Chanelle Pharmaceuticals Manufacturing Ltd.,
Loughrea,
Co. Galway,
Ireland.

Local representatives and contact details to report suspected adverse events:

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.