IRISH MEDICINES BOARD ACT 1995

EUROPEAN COMMUNITIES (ANIMAL REMEDIES) REGULATIONS 2007

(S.I. No. 144 of 2007)

VPA: **10879/032/002**
Case No: 7003369

The Irish Medicines Board in exercise of the powers conferred on it by Animal Remedies Regulations (S.I. No. 144 of 2007) hereby grants to:

Chanelle Animal Health Ltd.

7 Rodney Street, **Liverpool L1 9HZ**, **England**

an authorisation, subject to the provisions of the said Regulations and the general conditions of the attached authorisation, in respect of the Veterinary Medicinal Product:

Trostal 500mg Film Coated Tablets

The particulars of which are set out in Part 1 and Part 2 of the said Schedule. The authorisation is also subject to any special conditions as may be specified in the said Schedule.

Signed on behalf of the Irish Medicines Board

_____

A person authorised in that behalf by the said Board.

(NOTE: This authorisation replaces any previous authorisation in respect of this product which is now null and void.)

Part II

Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Trostal 500 mg film coated tablet.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains:

Active substance:			
Nitroscanate		500	mg
Excipients:			
Titanium Dioxide	(E171)	3.95	mg
Iron Oxide Yellow	(E172)	0.1306	mg
Iron Oxide Black	(E172)	0.00013	mg
Iron Oxide Red	(E172)	0.00013	mg

For a 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

Trostal 500 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 repeat treatment if vomiting occurs shortly after dosing. 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

Trostal 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.

4.5 Special precautions for use

Special precautions for use in animals

Administer with food (See 4.9)

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

Do not break the tablets.

4.6 Adverse reactions (frequency and seriousness)

When the product is not administered as recommended occasionally vomiting may occur.

4.7 Use during pregnancy, lactation or lay

Trostal 500 can be 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 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.

Trostal tablet(s) 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
ATC vet-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 alternations 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 level of 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 gastro intestinal tract, with increased contact time with the parasite.

5.2 Pharmacokinetic properties

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 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
Microcrystalline cellulose
Sodium starch glycollate
Sodium lauryl sulphate
Magnesium stearate
H.P.M.C. 2910 15cP
Polydextrose FCC
Polyethylene Glycol 4000
Titanium Dioxide (E171)
Iron Oxide Yellow (E172)
Iron Oxide Black (E172)
Iron Oxide Red (E172)

6.2 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 25ºC.

6.5 Nature and composition of immediate packaging

Aluminium Foil strips in outer carton.

100 tablets and 60 tablets (for veterinary surgeons only)
1 x 6 tablets
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

Any unused product or waste material should be disposed of in accordance with national requirements.

7 MARKETING AUTHORISATION HOLDER

Chanelle Animal Heatlh Ltd.,
7 Rodney Street,
Liverpool L1 9HZ,
England

8 MARKETING AUTHORISATION NUMBER(S)

VPA: 10879/32/2

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

6th July 2007

10 DATE OF REVISION OF THE TEXT

July 2007