

IRISH MEDICINES BOARD ACT 1995

ANIMAL REMEDIES REGULATIONS, 2005

(S.I. No. 734 of 2005)

VPA: **10835/013/001**

Case No: 7001565

The Irish Medicines Board in exercise of the powers conferred on it by Animal Remedies Regulations (S.I. No. 734 of 2005) hereby grants to:

Novartis Animal Health

Industrial Park, Cork Road, Waterford

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:

Lopatol 500mg Tablet

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 this

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

Lopatul 500mg Tablet

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains:

Active Substance:

Nitroscanate 500mg

For a full list of excipients see section 6.1.

3 PHARMACEUTICAL FORM

Tablet

4 CLINICAL PARTICULARS

4.1 Target Species

Dog

4.2 Indications for use, specifying the target species

Lopatul is a broad spectrum anthelmintic for use in dogs. It is highly effective against intestinal stages of the following nematodes and cestodes

Toxocara canis

Toxocaris leonina

Ancylostoma caninum

Uncinaria stenocephala

Taenia ovis

Taenia hydatigenia

Taenia pisiformis and Dipylidium caninum

4.3 Contraindications

Do not use in animals with known hypersensitivity to the active ingredient. Lopatul tablets are film coated and should not be broken or divided.

4.4 Special warnings for each target species

At the recommended dosage, Lopatul gives limited control of Echinococcus granulosus. The action of Lopatul against whipworms (Trichuris vulpis) is variable; a complete cure is obtained in some dogs, but only a reduction of the infestation in others. Since the prepatent period is so short for Dipylidium caninum there is a need for concomitant flea control with an appropriate product e.g. Nuvan Top.

4.5 Special precautions for use

Special precaution(s) for use in animals

None.

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

None known.

4.6 Adverse reactions (frequency and seriousness)

Lopatul when administered as recommended is unlikely to cause side effects. On rare occasions treated dogs may vomit, particularly if the feeding recommendation is not followed. This vomiting does not effect the anthelmintic efficacy of the product.

4.7 Use during pregnancy, lactation or lay

Treat breeding bitches after mating and shortly before and 4 weeks after whelping.

4.8 Interaction with other medicinal products and other forms of interaction

None known.

4.9 Amounts to be administered and administration route

For oral administration

For best results give Lopatul together with about one fifth of the daily food ration in the early morning when the dogs stomach is empty.

Give the remaining food ration in the evening.

Lopatul tablets should be given whole.

For routine treatment of puppies and adult dogs, the dose of Lopatul is 50 mg per kg (1 x 500 mg tablet per 10 kg bodyweight).

TREATMENT SCHEDULE

Pups: Should be de-wormed at the age of 2, 4, 6, 8 and 12 weeks in view of the danger of reinfestation.

Adult dogs: De-worming once or twice a year as prescribed by the vet.

Breeding bitches: Treat after mating and shortly before and 4 weeks after whelping.

Kennels: Because of the increased infestation risk it is recommended that all dogs in breeding kennels be de-wormed 4 to 6 times a year.

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

Most common signs observed after overdosing are vomiting, diarrhoea, tiredness and reduced appetite.

4.11 Withdrawal Period(s)

Not applicable.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

The active ingredient, Nitroscanate, is a broad-spectrum anthelmintic and is chemically described as a diphenylether derivative.

5.1 Pharmacodynamic properties

Nitroscanate depresses cellular energy production in vitro: Acid phosphatase, adenosine triphosphatase and fructose 1, 6-diphosphatase are inhibited. In addition, Nitroscanate decreases the ATP concentration and transiently increases lactate and acetate excretion. Furthermore, the glucose and glucose-6-phosphate pools are decreased where the pools of 3-phosphoglycerate, pyruvate and lactate are increased.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Methylcellulose
Colloidal Anhydrous Silica
Maize Starch
Microcrystalline Cellulose
Magnesium Stearate
Cellulose HP-M-603
Talc
Polyethylene glycol 8000

6.2 Incompatibilities

None known.

6.3 Shelf-life

The shelf life expiry date for this product shall not exceed five years from the date of its manufacture.

6.4 Special precautions for storage

Store in a dry place below 25°C.

6.5 Nature and composition of immediate packaging

Clinic pack containing 100 film coated biconvex tablets blistered in aluminium foil.

6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials

Unused product or waste material should be disposed of in accordance with current practice for pharmaceutical waste under national waste disposal regulations.

7 MARKETING AUTHORISATION HOLDER

Novartis Animal Health Ireland Ltd.,
Industrial Park,
Cork Road,
Waterford.

8 MARKETING AUTHORISATION NUMBER(S)

VPA: 10835/13/1

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

1st October 2004.