

IRISH MEDICINES BOARD ACT 1995

EUROPEAN COMMUNITIES (ANIMAL REMEDIES) (No. 2) REGULATIONS 2007

(S.I. No. 786 of 2007)

VPA: **10983/012/001**
Case No: 7006506

The Irish Medicines Board in exercise of the powers conferred on it by Animal Remedies (No. 2) Regulations (S.I. No. 786 of 2007) hereby grants to:

Vetoquinol Ireland Limited

10 Lad Lane, Lower Baggot Street, Dublin 2, Ireland

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:

Stromiten Dogs

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.

The authorisation, unless previously revoked, shall continue in force from **30/09/2009**.

Signed on behalf of the Irish Medicines Board

A person authorised in that behalf by the said Board.

(NOTE: From this date of effect, 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

Stromiten Dogs

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains:

Active Substance

Levamisole hydrochloride	19 mg
Niclosamide	720 mg

For a full list of excipients see section 6.1.

3 PHARMACEUTICAL FORM

Tablets

4 CLINICAL PARTICULARS

4.1 Target Species

Dogs.

4.2 Indications for use, specifying the target species

Stromiten is indicated for control and treatment of ascarids (*Toxocara*, *Toxascaris*), hookworm (*Ankylostoma*, *Uncinaria*) and tapeworm (*Taenia* spp., *Dipylidium caninum*).

4.3 Contraindications

Do not use in animals with known hypersensitivity to the active ingredients.

4.4 Special warnings for each target species

The product is not effective against *Echinococcus* spp or *Trichuris vulpis*.

4.5 Special precautions for use

Special precautions for use in animals

Do not administer in puppies younger than 3 months of age. As the administration of a large number of tablets could cause some distress and transient coughing in treated animals, the product is recommended only in dogs weighing less than 20 kg bodyweight.

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

None.

4.6 Adverse reactions (frequency and seriousness)

Rarely vomiting, stool softening and transitory coughing due to the administration of tablets may occur.

4.7 Use during pregnancy, lactation or lay

Do not administer to pregnant and lactating bitches.

4.8 Interaction with other medicinal products and other forms of interaction

Stromiten should not be administered concurrently with phenothiazine derivatives, parasympathomimetic drugs.

4.9 Amounts to be administered and administration route

For oral administration.

1 tablet per 4 kg bwt in a single administration. To be administered to fasted animals.

Levamisole (as hydrochloride): 4 mg/kg.

Niclosamide: 180 mg/kg.

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

Stromiten has a wide margin of safety. Few digestive disorders have been described.

4.11 Withdrawal Period(s)

Not applicable.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Antiparasitic products, insecticides and repellents, anthelmintics, imidazothiazoles, levamisole, combinations.

ATC vet code: QP52AE51

Niclosamide: non toxic taenicide when used at therapeutic doses. The taenicide effect leads to lysis of parasitic segments.

Levamisole: Tetramisole isomer, active on larval forms (non-encysted L4 and L5), and adults of many digestive and pulmonary nematodes.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Wheat Starch

Croscarmellose Sodium

Microcrystalline Cellulose

Magnesium Stearate

6.2 Incompatibilities

None known.

6.3 Shelf-life

Shelf life of the veterinary medicinal product as packaged for sale: 18 months.

6.4 Special precautions for storage

Store in a dry place.

6.5 Nature and composition of immediate packaging

Yellow convex tablets supplied in PVC aluminium blister, in a cardboard box of 12 or 96 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 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

Vetoquinol Ireland Limited
10 Lad Lane
Lower Baggot Street
Dublin 2
Ireland

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10983/012/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

30th September 2009

10 DATE OF REVISION OF THE TEXT