

IRISH MEDICINES BOARD ACT 1995

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

(S.I. No. 786 of 2007)

VPA: **10987/040/001**

Case No: 7006342

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:

Chanelle Pharmaceuticals Manufacturing Limited

Loughrea, Co. Galway, 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:

Gullivers Flea Shampoo

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

Gullivers Flea Shampoo

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Substances

Pyrethrins 0.05 % w/v

Piperonyl Butoxide 0.5 % w/v

Excipients

Bronidox L 0.20 % w/v

Amaranth (E123) 0.02 % w/v

Tartrazine (E102) 0.0005 % w/v

For a full list of excipients see section 6.1.

3 PHARMACEUTICAL FORM

Shampoo.

A wine coloured, thick solution.

4 CLINICAL PARTICULARS

4.1 Target Species

Dogs.

4.2 Indications for use, specifying the target species

For the control of fleas on dogs over six weeks of age.

4.3 Contraindications

Do not use in case of hypersensitivity to the active substances or to any of the excipients.

Do not use on cats.

Do not use on pups less than six weeks of age.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

Special precautions for use in animals

Not applicable.

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

Avoid ingestion.

If shampoo gets in contact with the eyes rinse with cold water.

Wash hands after use.

4.6 Adverse reactions (frequency and seriousness)

None known.

4.7 Use during pregnancy, lactation or lay

Can be used during pregnancy.

The safety of the veterinary medicinal product has not been established during lactation.

4.8 Interaction with other medicinal products and other forms of interaction

None known.

4.9 Amounts to be administered and administration route

For medium size dogs use 50 ml shampoo. Mix the measured amount of shampoo with 300 ml warm water. Wet coat thoroughly with warm water and apply half the mixture all over the body. Massage well into coat, use finger tips around head taking care to avoid eyes, ears and mouth. Rinse the coat and repeat the procedure using the remainder of the shampoo mixture. Rinse well with warm water and air dry.

Treatment may be repeated after 7 days if necessary.

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

Not applicable.

4.11 Withdrawal Period(s)

Not applicable.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Ectoparasiticides for topical use, incl. insecticides; combinations of pyrethrines.

ATC vet code: QP53AC30

Gullivers Flea Shampoo contains pyrethrins, insecticides that help reduce the ectoparasiticide population of fleas in dogs, in combination with a synergist piperonyl butoxide (in a 1 to 10 ratio) which enhances the activity of the pyrethrins.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Texapon N40 (Sodium lauryl ether sulphate)
Comperlan SD (Coconut fatty acid diethanolamine)
Cetiol HE (Polyol fatty acid ester)
Bronidox L (5-bromo-5-nitro-1,3-dioxane)
Sodium Chloride
Fragrance 362-979
Amaranth (E123)
Tartrazine (E102)
Purified water

6.2 Incompatibilities

None known.

6.3 Shelf-life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years.

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and composition of immediate packaging

250 ml high density transparent polythene bottles with polythene caps.

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

Do not contaminate ponds, waterways or ditches with the product or used containers.

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

Chanelle Pharmaceuticals Manufacturing Ltd.
Loughrea
Co. Galway

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10987/040/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

30th September 2009

10 DATE OF REVISION OF THE TEXT

