

IRISH MEDICINES BOARD ACT 1995

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

(S.I. No. 786 of 2007)

10881/016/001

Case No: 7005367

Transferred from 10833/001/001.

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

Wemberham Lane, Yatton, Somerset, BS49 4BS, United Kingdom

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:

Sergeants Pet Patrol Aerosol, %v/v

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 revoked, shall continue in force from **10/11/2008** until **30/11/2009**.

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

Sergeants Pet Patrol Aerosol

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Substance

Tetramethrin (90%)	0.1 % w/w
Phenothrin	0.2 % w/w
Piperonyl Butoxide BP (90%)	0.5 % w/w

Excipients

Odourless kerosene	39.2 % w/w
Butane 40	60.0 % w/w

For a full list of excipients see section 6.1.

3 PHARMACEUTICAL FORM

An insecticidal clear solution presented in an aerosol spray.

4 CLINICAL PARTICULARS

4.1 Target Species

Dogs and cats.

4.2 Indications for use, specifying the target species

For the topical treatment of flea infestation on cats and dogs for up to 15 days. The product has some efficacy against the flea egg and larval stages.

4.3 Contraindications

Do not use in animals with known hypersensitivity to the active ingredient.
Do not use on puppies or kittens under 12 weeks of age or on nursing bitches and queens.

4.4 Special warnings for each target species

Sick and convalescing animals must be treated by a veterinary surgeon.
Not for use on puppies or kittens under 12 weeks of age or on nursing bitches and queens. Remove fleas from young puppies, kittens, nursing bitches and queens by careful use of a comb.

4.5 Special precautions for use

Special precautions for use in animals

Dangerous to fish and aquatic vertebrates. Do not contaminate fish bowls, aquaria etc..

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

Wash hands and exposed skin after use.

Avoid inhaling spray mist.

Keep away from food or drink.

4.6 Adverse reactions (frequency and seriousness)

None.

4.7 Use during pregnancy, lactation or lay

Do not use in nursing bitches or queens.

4.8 Interaction with other medicinal products and other forms of interaction

None.

4.9 Amounts to be administered and administration route

For topical administration.

Apply the spray evenly to the animal against the natural lie of the coat. Use the aerosol at a distance of 15-20 cms (6-8 inches).

The recommended spraying time is:

DOGS: Spray for 3-5 seconds on a small dog (e.g. terrier). Spray for 10 seconds on a medium sized dog (e.g. collie). Spray for 15 seconds on a large dog (e.g. alsatian).

CATS: Spray for up to 3 seconds depending on the size of the cat.

Protection against reinfestation is usually retained for up to 15 days. Treatment may be repeated after 15 days if any reinfestation is apparent.

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

Treatment of the animal should not exceed once per 15 days.

4.11 Withdrawal Period(s)

Not applicable.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Insecticidal solutions.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Odourless kerosene
Butane 40

6.2 Incompatibilities

None known.

6.3 Shelf-life

1 year.

6.4 Special precautions for storage

Do not store above 25⁰C.

6.5 Nature and composition of immediate packaging

150ml tinplate cans, with valve and spray actuator, protected by a plastic cap.

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

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

7 MARKETING AUTHORISATION HOLDER

Bob Martin (UK) Limited
8 Wemberham Lane
Yatton
Somerset
BS49 4BS
United Kingdom

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10881/016/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

1st October 2004

10 DATE OF REVISION OF THE TEXT

November 2008