Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Beaphar Pump Action Flea Spray, Cutaneous Spray Solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substances

Pyrethrum extract 25% 1.027 % w/v Piperonyl butoxide 1.284 % w/v

Excipients

Citric acid, anhydrous (as antioxidant) 0.017 % w/v

For a full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Cutaneous spray, solution. Yellow, clear solution.

4 CLINICAL PARTICULARS

4.1 Target Species

Dogs and cats.

4.2 Indications for use, specifying the target species

Kills fleas (Ctenocephalides felis and Ctenocephalides canis) on dogs and cats.

4.3 Contraindications

Do not exceed recommended spray rate.

Do not use on young animals under 6 months of age.

Do not use on nursing females.

4.4 Special warnings for each target species

Remove fleas from young animals and nursing females by careful use of a flea comb.

Fleas from pets often infest animal baskets, bedding and regular resting areas, including carpets and soft furnishings, which should be treated with a suitable insecticide and vacuumed regularly.

If signs of disease persist or appear, consult your Veterinary Surgeon.

4.5 Special precautions for use

Special precautions for use in animals

For external use only.

Avoid spraying near the eyes, mouth and nostrils.

Keep treated animals away from fires and other sources of heat for at least 30 minutes following spraying and until coat is totally dry.

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

FLAMMABLE

Do not spray on a naked flame or any incandescent material.

Do not smoke when using this product.

Do not breathe spray mist and use in a well-ventilated area.

Avoid contact with eyes and mouth. In case of accidental eye contact, rinse with clean, fresh water. If eye irritation persists, seek medical advice.

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Persons who are hypersensitive (allergic) to pyrethrum extract should handle the product with care.

Treated animals should not be allowed to sleep or play with people, particularly children, until the animal is dry.

Keep away from food and drink, including animal feedingstuffs.

Wash hands and exposed skin after use.

Other precautions

Dogs should not be allowed to swim for 24 hours after application of the product.

Avoid spraying onto polished furniture and delicate fabrics.

4.6 Adverse reactions (frequency and seriousness)

Skin irritation may occur in sensitive individuals.

Occasionally, excessive salivation may occur in cats following use of the product as recommended. This effect is usually transient, but if noted consult your veterinary surgeon.

4.7 Use during pregnancy, lactation or lay

Do not use on nursing females.

4.8 Interaction with other medicinal products and other forms of interactions

Do not use with other topical treatments.

4.9 Amounts to be administered and administration route

For topical use only.

Cats: Brush the coat against its lie and spray no more than three times on each side, holding spray 15 inches (40 cm) from the cat, against the lie of the coat. Avoid eyes, nostrils and mouth. Lightly towel fur to remove any excess spray before allowing cat to groom.

Dogs: Brush the coat the wrong way and spray 15 inches (40 cm) from the coat, avoiding eyes, nostrils and mouth. Work from the rear of the head, squeezing the trigger the following number of times:-

Small dogs (1.5 - 5 kg) - 3 times each side Medium dogs (5.1- 15 kg) - 6 times each side Large dogs (15.1 - 30 kg) - 10 times each side

Repeat treatment in 4 to 5 days if necessary.

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

Symptoms: Hyperaesthesia, salivation, excitability, twitching, collapse.

Emergency procedures: Consult a veterinary surgeon.

Antidote: No specific antidote is known.

Treatment should be symptomatic and supportive.

4.11 Withdrawal period(s)

Not applicable.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

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

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5.1 Pharmacodynamic properties

Pyrethrins are insecticidal, acting on the sodium channels in the nerves, causing initial excitement and final paralysis. They remain active for 4 to 5 days following application.

5.2 Pharmacokinetic particulars

Pyrethrum, and its synergist piperonyl butoxide, have a non-systemic action, killing fleas when they come into contact with the insecticide present in the coat.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Isopropyl alcohol Citric acid anhydrous Water deionised

6.2 Major incompatibilities

None known.

6.3 Shelf-life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years.

6.4 Special precautions for storage

Protect from direct sunlight. Do not store above 25°C.

6.5 Nature and composition of immediate packaging

150 ml polyvinyl chloride bottle fitted with a polypropylene/low density polyethylene Calmer Albert finger activated pump (screw fit) delivering 0.1 ml per depression.

6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

Dangerous to fish and aquatic life. Do not contaminate aquaria, fish bowls, ponds or other waterways with the product or used containers.

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7 MARKETING AUTHORISATION HOLDER

Beaphar B.V. Drostenkamp 3 PO Box 7 8100 AA Raalte Netherlands

8 MARKETING AUTHORISATION NUMBER(S)

VPA10455/005/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 01 October 1989 Date of last renewal: 30 September 2009

10 DATE OF REVISION OF THE TEXT

March 2019

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