

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Beaphar Pump Action Flea Spray for Cats and Dogs, Cutaneous Spray Solution

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

<u>Active substance</u>	<u>% w/v</u>
Pyrethrum Extract 25%	1.027
Piperonyl butoxide	1.284

Excipients

Citric acid, anhydrous (as antioxidant)	0.017
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For 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 Contra-indications

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

i. 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.

ii Special precautions to be taken by the person administering the 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.

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 feeding stuffs.

Wash hands and exposed skin after use.

iii 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 interaction

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 PROPERTIES

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

ATCvet code: QP53AC51

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

Citric acid, anhydrous
Isopropyl alcohol
Water Deionised

6.2 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, if appropriate

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

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

7. MARKETING AUTHORISATION HOLDER

Beaphar UK Ltd
Rook Tree Farm
Withersfield Road
Great Wratting
Suffolk
CB9 7HD

8. MARKETING AUTHORISATION NUMBERS

Vm 13907/4000

9. DATE OF FIRST AUTHORISATION

29 September 1994

10. DATE OF REVISION OF THE TEXT

June 2018

A handwritten signature in black ink, consisting of several stylized, overlapping loops and a long, sweeping tail that curves downwards and to the right.

Approved 07 June 2018