

1. Name of the Veterinary Medicinal Product

Johnson's Dog Flea Pump Spray, Cutaneous Spray Solution

2. Qualitative and Quantitative Composition

<u>Active substance</u>	<u>% w/w</u>
Pyrethrum Extract 25%	1.00
(equivalent to Pyrethrins	0.25)
Piperonyl butoxide	1.25

For full list of excipients, see section 6.1.

3. Pharmaceutical form

Cutaneous Spray, Solution
Pale yellow, clear 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.

4.3 Contra-indications

Do not use on puppies under 12 weeks of age.
Do not use on nursing females.

4.4 Special warnings for each target species

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

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

If signs of disease persist or appear, consult a veterinary surgeon.

4.5 Special precautions for use

(i) Special precautions for use in animals

For external use only.
Avoid the eyes.

(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. In case of accidental eye contact, rinse with clean, fresh water. If eye irritation persists, seek medical advice.

Wash hands and exposed skin after use.
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.

(iii) Other precautions

Do not allow treated dogs to swim for 24 hours after application of the product.

4.6 Adverse reactions (frequency and seriousness)

None reported.

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 any other insecticide on the dog within 7 days of treatment.

4.9 Amounts to be administered and administration route

Remove the protective cover. Comb the animal's coat the wrong way and spray into the roots of the coat and the skin from a distance of about 15 cm (6 inches) working from the rear to the head. Avoid the eyes and other sensitive areas. Comb the coat back into place and towel lightly to remove all excess spray. **DO NOT ALLOW THE DOG TO GROOM UNTIL THIS IS DONE AND THE COAT IS DRY.** Keep treated animals away from fires and other sources of heat for at least 30 minutes following spraying and until the coat is totally dry. Repeat after 3 – 4 days if any reinfestation is apparent.

Recommendation:

Use 25 pumps of the spray for a small dog (e.g. terrier)

Use 35 pumps of the spray for a medium sized dog (e.g. collie)

Use 50 pumps of the spray for a large dog (e.g. Alsatian)

Do not exceed the recommended dosage.

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

In case of an adverse reaction, consult a veterinary surgeon. Treat symptomatically.

4.11 Withdrawal period(s)

Not applicable.

5 Pharmacological properties

Pharmacotherapeutic group: Ectoparasiticides for topical use, incl. insecticides

ATCvet code: QP53AC51

5.1 Pharmacodynamic properties

The spray contains the active ingredient Pyrethrins (from Pyrethrum Extract 25%).

Pyrethrum is rapidly toxic to many insects including fleas.

5.2 Pharmacokinetic particulars

The pyrethroids possess potent insecticidal activity with much lower mammalian toxicity.

6 Pharmaceutical particulars

6.1 List of excipients

Isopropyl alcohol

Water Potable

6.2 Incompatibilities

None known.

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 5 years.

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and composition of immediate packaging

100 ml or 200 ml of product contained within a white high-density polyethylene bottle fitted with a fingertip pump dispenser delivering 190 microlitres per pump depression. The bottle is labelled according to the conditions of the marketing authorisation.

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.

DANGEROUS to fish and aquatic life. Do not spray in areas containing aquaria, fish tanks and bowls. Do not contaminate ponds, waterways or ditches with the product or empty packaging.

7 Marketing authorisation holder

Sinclair Animal and Household Care Ltd.

Ropery Road

Gainsborough

Lincolnshire

DN21 2QB

8 Marketing authorisation number

Vm 16516/4019

9 Date of first authorisation/date of renewal of the authorisation

Date of first authorisation: 6 June 1991

10 Date of revision of text

July 2008