SUMMARY OF PRODUCT CHARACTERISTICS

1. Name of the Veterinary Medicinal Product:

Johnson's Dog Flea Spray, cutaneous spray, solution.

2. Qualitative and Quantitative Composition:

Pyrethrum Extract 25% 0.8% w/w Piperonyl Butoxide 1.0% w/w

For full list of excipients, see section 6.1.

3. Pharmaceutical form:

Cutaneous spray, solution. A clear, yellow liquid.

4. <u>Clinical particulars:</u>

4.1 Target species:

Dogs and puppies over 12 weeks of age, also cats over 12 weeks of age with caution.

4.2 <u>Indications for use, specifying the target species:</u>

Insecticidal spray to kill fleas on dogs, puppies and cats over 12 weeks of age.

4.3 Contra-Indications:

Do not use on animals under 12 weeks of age or on nursing bitches or queens.

4.4 Special warnings for each target species:

CATS: Spray cats for 3-5 seconds (NO MORE) according to size, then comb coat back into place and towel lightly to remove excess Spray. Do not allow cat to groom until this has been done and coat is dry. Cats should not be allowed to lick the hair of treated dogs.

DOGS & CATS:

HAZARD WARNING: Keep treated animals away from fires and other sources of heat for at least 30 minutes following spraying and until the fur is totally dry.

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

May cause gastric irritation and nervous signs if ingested. (See also

5.9).

4.5 i) Special precautions for use in animals:

For external use only.

4.5 ii) Special precautions to be taken by the person administering the medicinal product to animals:

Do not breathe spray mist.

Use in well ventilated area.

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

Do not smoke when using this product.

Avoid contact with eyes. 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.

4.6 Adverse reactions (frequency and seriousness)

None reported.

4.7 Use during pregnancy, lactation or lay:

Do not use on nursing bitches or queens.

4.8 Interaction with other medicinal products and other forms of interaction:

None reported.

4.9 Amounts to be administered and administration route:

Directions for use: Shake can before use. Spray from a distance of about 12" (30cm), all over body, commencing at tail, while brushing against lie of coat to permit spray penetration. Avoid eyes and other sensitive areas. Repeat every 3-4 days if necessary until infestation is cleared. Keep animal under observation for 30 minutes after treatment, then brush and comb to remove dead fleas.

Dogs: Spray small dogs for about 6 seconds, medium dogs for about 9 seconds and large dogs for about 14 seconds.

Cats: May be used with caution on cats over 12 weeks of age, but spray only for 3-5 seconds (no more) according to size. Comb coat back into place and towel lightly to remove all excess spray. Do not allow cat to groom until this has been done and coat is dry. Some cats are sensitive to aerosols, in which case use a cat flea powder or cat flea collar.

Fleas from pets often infest animal's basket, bedding and regular resting areas such as carpets and soft furnishings which should be treated with a suitable insecticide and vacuumed regularly. Wash or change pet bedding regularly.

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

Hypersalivation, vomiting, diarrhoea and nervous signs are reported. Tranquillisers may be used to control CNS effects.

4.11 Withdrawal periods:

Not applicable.

5. <u>Pharmacological properties:</u>

ATC Vet code: QP53AC51

5.1 <u>Pharmacodynamic properties:</u>

Pyrethrins/Piperonyl Butoxide

The plant Pyrethrum is a chrysanthemate; the powdered, dried flower heads contain active principles mainly in the form of pyrethrins. Pyrethrins have insecticidal activity producing both knock-down and mortality in a range of insects, and low mammalian toxicity. Common names: Dalmatian insect powder and Persian insect powder.

Piperonyl butoxide acts as a synergist when combined with pyrethrin and prolongs its action.

5.2 Pharmacokinetic particulars:

No other information available.

6. Pharmaceutical particulars:

6.1 List of excipients:

Kerosene Odourless Isopropyl Alcohol Propane/Isobutane/Butane 30 Propellant

6.2 Incompatibilities:

None known.

6.3 Shelf-life:

Shelf life of the veterinary medicinal product as packaged for sale: 30 months.

6.4 Special precautions for storage:

Extremely flammable. Pressurised container: Protect from sunlight and do not expose to temperatures exceeding 50°C. Do not pierce or burn even after use. Do not spray on a naked flame or any incandescent material. Keep away from sources of ignition – No smoking. Do not store above 25°C.

6.5 Nature and composition of immediate packaging:

Pack Size: 150ml (95g)

250ml (157g)

Container: Unlined tinplate aerosol can.

Closure: Aerosol valve assembly capable of delivering 0.85g

of product per second.

Not all pack sizes may be marketed.

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

Harmful to fish and crustaceans. Do not contaminate aquaria and fish bowls with the product.

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

7.0 Marketing Authorisation holder:

Johnson's Veterinary Products Ltd 5 Reddicap Trading Estate Sutton Coldfield West Midlands B75 7DF

8. <u>Marketing Authorisation number:</u>

Vm01759/4045

9. Date of first Authorisation:

08.10.91

10. Date of revision of the text:

26.08.08