JOHNSON'S VETERINARY PRODUCTS LTD

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF PRODUCT:

Johnson's Puppy Flea Powder.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION:

Active Ingredients:

Pyrethrum Powder 1.3% w/w (to give 0.1% w/w Pyrethrins) 8.17% w/w * Piperonyl Butoxide 0.80% w/w

3. PHARMACEUTICAL FORM:

Cutaneous powder.

4. PHARMACOLOGICAL PROPERTIES:

Pyrethrins/Piperonyl Butoxide

Pyrethrum is a chrysanthemum derivative; 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. <u>CLINICAL PARTICULARS:</u>

5.1 <u>Target Species:</u>

Puppies over 12 weeks of age and young dogs.

5.2 <u>Indications for Use:</u>

Insecticidal powder to kill fleas on puppies over 12 weeks of age and young dogs.

5.3 Contra-Indications:

Do not use on puppies under 12 weeks of age or on nursing bitches. If signs of disease persist or appear, consult a Veterinary Surgeon promptly.

5.4 Undesirable effects:

None.

5.5 Special Precautions for Use:

For external use only.

5.6 Use during pregnancy and lactation:

Do not use on nursing bitches.

^{*} Includes 5% stability overage.

5.7 Interaction with other medicaments and other forms of interaction:

None reported.

5.8 <u>Posology and method of administration:</u>

Directions for use: Use when coat is dry, in open air if possible. Apply powder evenly all over body commencing at tail while stroking against lie of coat to ensure that powder reaches the skin. Use 5-10g for a small dog, 10-15g for a medium dog, 15-20g for a large dog. Avoid eyes, nose and mouth. Leave for 30 minutes then comb or brush thoroughly. Repeat every 3-4 days if necessary, until infestation is cleared.

This pack contains sufficient powder to treat a small dog (e.g. 4-6kg) 7-8 times, a medium sized dog (e.g. 10-15kg) 4-6 times and a large dog (e.g. 25-35kg) 3-4 times.

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.

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

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

None stated.

5.10 Special warnings for each target species:

None stated.

5.11 Withdrawal periods:

Not applicable to companion animals.

5.12 Special precautions to be taken by the person administering the product to animals:

Avoid inhaling powder. Avoid contact with eyes. Wash hands after use. Keep away from food and drink.

6. PHARMACEUTICAL PARTICULARS:

6.1 <u>Incompatibilities (major):</u>

6.2 Shelf-life:

30 months.

6.3 Special precautions for storage:

Do not store above 25°C. Store in a dry place.

6.4 <u>Nature and contents of container:</u>

Pack Size: 55g

Container: White HDPE or polypropylene puffer bottle with one hole LDPE plug

Closure: White polypropylene screw cap with spigot.

6.5 Special precautions for the disposal of unused product or waste materials, if any:

None.

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

7.0 Name and Address of Licence Holder/Marketing Company:

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

MA No. **Vm**.01759/4043

Date of last revision of SPC: 22.10.03 Date Renewal issued: 10.09.03

Conditions of supply: GSL

May be sold or supplied otherwise than by or under the supervision of a pharmacist as a medicinal product on a General Sales List.

Issue No.	Date Issued:	Signed:	Position:	Reason for Issue:
04	22.10.03		QP	Revised sections: 2, 3, 4, 5, 6.2, 6.3, 6.5 and 7.0