

SUMMARY OF PRODUCT CHARACTERISTICS

1. Name of the Veterinary Medicinal Product:

Johnson's Dog Flea Powder, Cutaneous Powder.

2. Qualitative and Quantitative Composition:

Active substance

| <u>Qualitative composition</u> | <u>Quantitative composition % w/w</u> |
|---------------------------------------|---------------------------------------|
| Pyrethrins (From Pyrethrum Powder) | 0.1 (1.3) |
| Piperonyl Butoxide | 0.8 |

Excipients

For full list of excipients, see section 6.1.

3. Pharmaceutical form:

Cutaneous powder.
Free flowing white/grey powder, perfumed.

4. Clinical particulars:

4.1 Target species:

Dogs and Puppies over 12 weeks of age.

4.2 Indications for use, specifying the target species:

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

4.3 Contra-Indications:

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

4.4 Special warnings for each target species:

None stated.

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:

Avoid inhaling the powder. Use in a well ventilated area.

Wash hands and exposed skin after use.

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 powder has been brushed out. Keep away from food and drink, including animal feeding stuffs.

4.6 Adverse reactions (frequency and seriousness)

None reported.

4.7 Use during pregnancy, lactation or lay:

Do not use on nursing bitches.

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: 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.

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.

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

None stated.

4.11 Withdrawal periods:

Not applicable.

5. Pharmacological properties:

ATC Vet code: QP53AC51

5.1 Pharmacodynamic properties:

Pyrethrum is a chrysanthemum; 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:

Magnesium Carbonate Light
Perfume F521.213
Silicon Dioxide Precipitated
Talc Substitute XF*

* Aluminium silicate combined with sericitic Mica and Chlorite

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:

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

6.5 Nature and composition of immediate packaging:

White high density polyethylene or polypropylene puffer bottle with a white polypropylene flip top cap (screw fit) with spigot.

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. Marketing Authorisation number(s):

01759/4040

9. Date of first Authorisation:

07.08.91

10. Date of revision of the text:

10.09.08