

JOHNSON'S VETERINARY PRODUCTS LTD

SUMMARY OF PRODUCT CHARACTERISTICS

1. Name of the Veterinary Medicinal Product:

Johnson's Dog Flea Shampoo

2. Qualitative and Quantitative Composition:

Qualitative composition

Quantitative composition % w/w

Active Ingredients:

Pyrethrum Extract (25%)	0.19%
[equivalent to pyrethrins	0.0475%]
Piperonyl Butoxide Technical	0.49%

Excipients:

Bronidox L	0.13
Carmoisine (E122)	0.0032

For full list of excipients, see section 6.1.

3. Pharmaceutical form:

Shampoo.

Clear, red viscous liquid shampoo with characteristic odour.

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 shampoo 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.
Do not use on cats.

4.4 Special warnings for each target species:

Pets' bedding and locations frequently used in the house should be treated with a suitable insecticide and vacuumed regularly.

4.5 Special precautions for use:

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 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 especially 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.

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: Mix shampoo (about 50ml for a medium sized dog) into about 300ml warm water (approx 2 fl.oz. to half-pint). Wet dog's coat thoroughly with warm water and apply half the mixture all over the body. Massage well into coat, but use finger tips around the head, taking care to avoid eyes, ears and mouth. Rinse and repeat with remainder of mixture, for good lather. Finally rinse well, towel dry, then brush and comb thoroughly. Repeat in 7 days if necessary.

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.

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:

Pyrethrins/Piperonyl Butoxide

The plant 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:

Bronidox L
Carmoisine (E122)
Sodium Lauryl Ether Sulfate
Coconut Diethanolamide
Solan E50
Perfume Bouquet 70012
Sodium Chloride
Citric Acid Monohydrate
Water, potable

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:

Do not store above 25°C.
Protect from frost.
Protect from direct sunlight.

6.5 Nature and composition of immediate packaging:

Pack Size: 125ml, 200ml, 400ml and 5 litre
Container: Clear polyvinyl chloride bottle
Closure: White polypropylene flip top closure cap with spigot.

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 or fishbowls with the product.

Dispose of any waste water on to soil not used for growing vegetables.

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):

Vm01759/4048

9. Date of first Authorisation:

18.01.92

10. Date of revision of the text:

13.08.08

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