SUMMARY OF PRODUCTS CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Johnson's 4Fleas shampoo for dogs 1.05% w/v

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Qualitative composition	Quantitative composition
Active substance:	Active substance:
Permethrin cis:trans 25;75	1.05% w/v
Excipients:	Excipients:
Tartrazine E102 (colour)	0.0022% w/v
Amaranth E123 (colour)	0.0004% w/v
Formaldehyde solution (35% w/w) (preservative)	0.21% w/v

For full list of excipients, see Section 6.1.

3. PHARMACEUTICAL FORM

Shampoo
A clear orange coloured, odourless viscous 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 over 12 weeks of age.

4.3 Contraindications

Do not use on puppies under 12 weeks of age.
DO NOT USE ON CATS.
Do not use on nursing bitches.

4.4 Special warnings for each target species

None

4.5 Special precautions for use

i. Special precautions for use in animals

For external use only.
Avoid contact with eyes.

ii. Special precautions for the person administering the veterinary medicinal product to animals

Wash hands and exposed skin after use.
Avoid prolonged contact with skin. It is advisable to wear gloves whilst 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.
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.

4.6 Adverse reactions (frequency and seriousness)

None.

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.

4.9 Amount(s) to be administered and administration route

30ml to be used for a medium sized dog.

Add directly to a wetted coat or add 30ml to 600ml of water before use. Work into the coat, leave for 2 minutes and rinse. Allow to dry naturally.
If necessary repeat after seven days or until infestation is cleared.
Remove fleas from young puppies and nursing bitches by careful use of a flea comb.
Fleas from pets often infest animal's basket and regular resting areas such as carpets and soft furnishings which should be treated with a suitable insecticide and vacuumed regularly.

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

Dogs treated with 3 x the recommended dose showed no signs of clinical toxicity or irritation.

4.11 Withdrawal period(s)

Not applicable.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: antiparasitic agent

ATC Vet Code: QP53AC04

5.1 Pharmacodynamic properties

Permethrin is a contact ectoparasitacide acting on the sodium channel. It attacks the peripheral nervous system and in particular the motor nerve terminals in the central nervous system. Broadly speaking, Permethrin causes knockdown in arthropods, inducing loss of coordination, spasms, tremors and ultimately, death.

5.2 Pharmacokinetic properties

If permethrin is orally administered to mammals it is rapidly metabolized and almost completely excreted via urine or faeces within a short period of time. The trans isomer is eliminated faster then the cis isomer, it being the more susceptible of the two to esterase attack. The major metabolic reactions are ester hydrolysis, ester cleavage, oxidation and conjugation. Permethrin does not have a tendency to accumulate in tissues. None of the metabolites of permethrin show a higher acute toxicity then the base permethrin. Given that this product is administered externally, absorption rates are considerably lower than when administered orally.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Tartrazine E102
Amaranth E123
Formaldehyde solution (35% w/w)
Sodium lauryl ether sulphate
Coconut diethanolamide
Polyoxyethylated castor oil
Water purified
Citric acid monohydrate

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

Protect from frost. Protect from direct sunlight. Store in an upright position in a dry place.

6.5 Nature and composition of immediate packaging

Size: 100ml, 240ml and 5 litre
Container: White high density polyethylene bottle.
Closures: Polypropylene screw cap-closure.

Not all pack sizes may be marketed.

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

Harmful to fish and crustaceans. Do not contaminate aquaria or fish bowls with the product. Dispose of 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. MARKETING AUTHORISATION HOLDER

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

8. MARKETING AUTHORISATION NUMBER

Vm 01759/4077

9. DATE OF FIRST AUTHORISATION

06/08/2003

10. DATE OF REVISION OF THE TEXT

September 2010