

## **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

Active substance:

Permethrin cis:trans 25;75

Excipients:

Tartrazine E102 (colour)

Amaranth E123 (colour)

Formaldehyde solution (35% w/w)  
(preservative)

For full list of excipients, see Section  
6.1.

#### Quantitative composition

Active substance:

1.05% w/v

Excipients:

0.0022% w/v

0.0004% w/v

0.21% w/v

### **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 ectoparasiticide 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 than 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 than 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