

## **SUMMARY OF PRODUCTS CHARACTERISTICS**

### **1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Johnson's 4Fleas powder for cats and dogs 1.05% w/w Cutaneous powder

### **2. QUALITATIVE AND QUANTITATIVE COMPOSITION**

#### Qualitative composition

Permethrin cis:trans 25;75

#### Quantitative composition

Permethrin 1.05% w/w.

For full list of excipients, see section 6.1.

### **3. PHARMACEUTICAL FORM**

Cutaneous powder.  
Off white fine powder.

### **4. CLINICAL PARTICULARS**

#### **4.1 Target species**

Cats and dogs.

#### **4.2 Indications for use, specifying the target species**

For the control of fleas on dogs and cats.

#### **4.3 Contraindications**

Do not use on puppies under 12 weeks of age or kittens under 2 weeks of age.  
Do not use on nursing females.

#### **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.

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

Use in a well ventilated area.

Avoid inhaling the powder.

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.

If you feel unwell as a result of handling this product, you should consult your Doctor.

Treated animals should not be allowed to sleep or play with people, particularly children, until the powder has been brushed out.

#### **4.6 Adverse reactions (frequency and seriousness)**

None.

#### **4.7 Use during pregnancy, lactation or lay**

Do not use on nursing females.

#### **4.8 Interaction with other medicinal products and other forms of interaction**

None.

#### **4.9 Amount(s) to be administered and administration route**

5-10g to be used for a small dog.

10-15g to be used for a medium sized dog.

15-20g to be used for a large dog.

5-9g to be used on cats according to size.

Shake gently before use. Dust evenly over the whole body whilst stroking or brushing against the lie of the hair to ensure powder penetrates to the skin.

Avoid getting powder into animal's eyes, nose or mouth. Brush off excess powder.

The pack contains sufficient powder to treat a medium sized dog 6 – 8 times. If necessary repeat every 7 days until infestation is cleared.

Remove fleas from young puppies, kittens and nursing bitches and females by careful use of a flea comb.

Fleas from pets often infest animals' basket, bedding 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**

Cats and dogs treated with 3 x the recommended dose showed no signs of clinical toxicity or irritation. Signs of overdose include hyperaesthesia, twitching and collapse. Treatment is symptomatic.

#### **4.11 Withdrawal period(s)**

Not applicable.

### **5. PHARMACOLOGICAL PROPERTIES**

#### **Pharmacotherapeutic group:**

Ectoparasiticides, insecticides and repellents, Ectoparasiticides for topical use, incl. insecticides, Pyrethrins and pyrethroids

**ATC Vet Code:** QP53AC05.

#### **5.1 Pharmacodynamic properties**

Permethrin, like other synthetic pyrethroids, is a neuropoison acting on the axons in the peripheral and central nervous system by interacting with sodium channels.

#### **5.2 Pharmacokinetic properties**

When 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 orally administered.

### **6. PHARMACEUTICAL PARTICULARS**

#### **6.1 List of excipients**

Purified Siliceous earth.  
Talc Purified

#### **6.2 Incompatibilities**

None known.

### **6.3 Shelf life**

Shelf life of the veterinary medicinal product as packaged for sale: 3 years.

### **6.4 Special precautions for storage**

Store away from food, drink and animal feeding stuffs.  
Store in a dry place.

### **6.5 Nature and composition of immediate packaging**

Size: 85g

Container: White high density polyethylene bottle with sifter top.

Closures: White polypropylene screw cap-closure (push fit).

### **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.

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**

Bio-Tech Solutions Ltd.  
Windmill Works  
Kelleythorpe Industrial Estate  
Driffield  
East Yorkshire  
YO25 9DJ

## **8. MARKETING AUTHORISATION NUMBER**

**Vm** 20889/4002

## **9. DATE OF FIRST AUTHORISATION**

**Date:** 6.8.2003

## **10. DATE OF REVISION OF THE TEXT**

**Date:** February 2010