

**PARTICULARS TO APPEAR ON <THE OUTER PACKAGE> > {Label}**

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

Johnson's Veterinary Dog Flea Shampoo

**2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES**

Contains: Pyrethrum extract (25%) 0.19% w/w  
to give 0.0475% w/w Pyrethrins  
Piperonyl Butoxide 0.49% w/w

**3. PHARMACEUTICAL FORM**

Shampoo. Clear, red viscous liquid shampoo with characteristic odour.

**4. PACKAGE SIZE**

125ml, 200ml, 400ml, 5 litre.

**5. TARGET SPECIES**

Dogs and Puppies over 12 weeks of age

**6. INDICATION(S)**

kills fleas on dogs and puppies over 12 weeks of age.

**7. METHOD AND ROUTE(S) OF ADMINISTRATION**

**Directions:** Mix Shampoo (50ml for medium-size dog) into 300ml warm water. Wet coat thoroughly with warm water and apply half the mixture all over the body. Massage well into coat, but use finger tips around 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. Keep pets warm after bathing.

**8. WITHDRAWAL PERIOD**

Not applicable.

## 9. SPECIAL WARNING(S), IF NECESSARY

**Contra-Indications:** Do not use on Cats. Do not use on Puppies under 12 weeks of age or nursing Bitches, from which fleas may be removed by careful use of a flea comb. If symptoms persist or appear, consult a Veterinary Surgeon promptly.

**Operator Warnings:** 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 feedingstuffs. Wash hands and exposed skin after use.

## 10. EXPIRY DATE

End mm/yy

## 11. SPECIAL STORAGE CONDITIONS

For external use only. For animal treatment only. Keep out of reach of children. Protect from frost and direct sunlight. Do not store above 25°C.

## 12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

**Disposal Advice:** Harmful to fish and crustaceans. Do not contaminate aquaria or fish bowls with the product. Dispose of any waste water on to soil not used for growing vegetables. Dispose of empty packaging and any remaining product in the household refuse.

## 13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE [*Distribution category*]

AVM-  
GSL

## 14. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of reach of children

## 15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Johnson's Veterinary Products Limited

5 Reddicap Trading Estate

Sutton Coldfield, West Midlands

B75 7DF. UK

**16. MARKETING AUTHORISATION NUMBER(S)**

**Vm** 01759/4048

**17. MANUFACTURER'S BATCH NUMBER**

**MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING  
UNITS {NATURE/TYPE}**

- 1. NAME OF THE VETERINARY MEDICINAL PRODUCT**
  
- 2. QUANTITY OF THE ACTIVE SUBSTANCE(S)**
  
- 3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES**
  
- 4. ROUTE(S) OF ADMINISTRATION**
  
- 5. WITHDRAWAL PERIOD**
  
- 6. BATCH NUMBER**
  
- 7. EXPIRY DATE**
  
- 8. THE WORDS “FOR ANIMAL TREATMENT ONLY”**

**MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS**  
**{NATURE/TYPE}**

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

**2. NAME OF THE MARKETING AUTHORISATION HOLDER**

**3. EXPIRY DATE**

**4. BATCH NUMBER**

**5. THE WORDS “FOR ANIMAL TREATMENT ONLY”**

## **PARTICULARS TO APPEAR ON THE IMMEDIATE DILUENT LABEL**

### **1. NAME OF THE DILUENT**

*The 'trade' name with a brief description or a more describing way of naming (Solvent /diluent for type of vaccine it can be used with or properties of the diluent).*

### **2. CONTENT BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES**

### **3. ROUTES OF ADMINISTRATION**

*[According to "Standard terms" published by the Council of Europe. See also QRD reference document "Tables of non-standard abbreviations".]*

Read the package leaflet before use.

### **4. STORAGE CONDITIONS**

<Do not store above <25 °C> <30 °C>.>  
<Store below <25 °C> <30 °C>.>  
<Store in a refrigerator.>  
<Store and transport refrigerated.>\*  
<Store in a freezer.>  
<Store and transport frozen.>\*\*  
<Do not <refrigerate> <or> <freeze>.>  
<Protect from frost.>\*\*\*  
<Store in the original <container><package>.>  
<Keep the {container}\*\*\*\* tightly closed.>  
<Keep the {container}\*\*\*\* in the outer carton.>  
<in order to protect from <light> <and> <moisture>>  
<Protect from light.>  
<Store in a dry place.>  
<Protect from direct sunlight.>  
<This veterinary medicinal product does not require any special storage conditions.>  
<This veterinary medicinal product does not require any special temperature storage conditions.>

### **5. BATCH NUMBER**

<Batch> <Lot> <BN> {number}

### **6. EXPIRY DATE**

<EXP {month/year}>

### **7. THE WORDS "FOR ANIMAL TREATMENT ONLY"**

**[Include information under these headings as it appears in the SPC]**

**PACKAGE LEAFLET FOR:**

**1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT**

**2. NAME OF THE VETERINARY MEDICINAL PRODUCT**

**3. STATEMENT OF THE ACTIVE SUBSTANCE (S) AND OTHER INGREDIENTS**

**4. INDICATION(S)**

**5. CONTRAINDICATIONS**

**6. ADVERSE REACTIONS**

**7. TARGET SPECIES**

**8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION**

**9. ADVICE ON CORRECT ADMINISTRATION**

**10. WITHDRAWAL PERIOD(S)**

## 11. SPECIAL STORAGE PRECAUTIONS

**[Pharmaceuticals ONLY - The following statement should be included if there is an in-use shelf life (example: solution for injection)]**

<When the container is broached/opened for the first time, using the in-use shelf-life which is specified on this package leaflet, the date on which any product remaining in the container should be discarded should be determined. This discard date should be written in the space provided.>

## 12. SPECIAL WARNING(S)

<User Warnings>

For Animal Treatment Only

**[Immunologicals ONLY - For injectables containing mineral oil, the following statement should be included:]**

<To the user:

This product contains mineral oil. Accidental injection/self injection may result in severe pain and swelling, particularly if injected into a joint or finger, and in rare cases could result in the loss of the affected finger if prompt medical attention is not given.

If you are accidentally injected with this product, seek prompt medical advice even if only a very small amount is injected and take the package insert with you.

If pain persists for more than 12 hours after medical examination, seek medical advice again.

To the physician:

This product contains mineral oil. Even if small amounts have been injected, accidental injection with this product can cause intense swelling, which may, for example, result in ischaemic necrosis and even the loss of a digit. Expert, PROMPT, surgical attention is required and may necessitate early incision and irrigation of the injected area, especially where there is involvement of finger pulp or tendon.>

## 13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY



Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

**14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED**

*[It is recommended that the following reference to the VMD Website is included:]*

<Find more product information by searching for the 'Product Information Database' or 'PID' on [www.gov.uk](http://www.gov.uk).>

**<15. OTHER INFORMATION>**

[Distribution category]

*Vm <number>*

**MINIMUM PARTICULARS TO APPEAR ON THE LABEL WHERE THERE IS NO PACKAGE LEAFLET, E.g. Concertina Labels. {NATURE/TYPE}**

*[The guidance contained below is national specific only and should be used in addition to EU QRD template guidance for both the Package Leaflet AND the Outer/Immediate package, available on the EMA website.]*

**1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT**

**2. NAME OF THE VETERINARY MEDICINAL PRODUCT**

**3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENTS**

**4. PHARMACEUTICAL FORM**

**5. PACKAGE SIZE**

**6. INDICATION(S)**

*[Optional. In case of space restriction and if the indication is clear from the name of the product, the indication should not be repeated]*

**7. CONTRAINDICATIONS**

**8. ADVERSE REACTIONS**

**9. TARGET SPECIES**

**10. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION**

**11. ADVICE ON CORRECT ADMINISTRATION**

**12. WITHDRAWAL PERIOD**

**13. SPECIAL STORAGE PRECAUTIONS**

Keep the container in the outer carton.

**[Pharmaceuticals ONLY - The following statement should be included if there is an in-use shelf life (example: solution for injection)]**

<When the container is broached/opened for the first time, using the in-use shelf-life which is specified on this package leaflet, the date on which any product remaining in the container should be discarded should be determined. This discard date should be written in the space provided.>

**14. SPECIAL WARNING(S)<User Warnings>**

**15. EXPIRY DATE**

**16. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY**

**17. DATE ON WHICH THE LABEL WAS LAST APPROVED**

*[It is mandatory for Exceptional Marketing Authorisations and recommended for others that the following reference to the VMD Website is included:]*

<Find more product information by searching for the Product Information Database 'PID' on [www.gov.uk](http://www.gov.uk).>

**18. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE**

*[Distribution category]*

POM-V

POM-VPS

NFA-VPS

AVM-GSL

**19. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”**


**20. MARKETING AUTHORISATION NUMBER(S)**

Vm <number>

**21. MANUFACTURER’S BATCH NUMBER**

**<22. OTHER INFORMATION>**

**Approved: 01/08/2017**

A handwritten signature in black ink, appearing to read 'J. J. J.', is positioned below the approval date.