

## **PARTICULARS TO APPEAR ON <THE IMMEDIATE PACKAGE>**

**{Label }**

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

Armitage Pet Care Insecticidal Flea Shampoo & Conditioner

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

What's in this shampoo?

Contains Pyrethrins 0.0475% w/w (present as Pyrethrum Extract 25%) and Piperonyl Butoxide 0.49% w/w

### **3. PHARMACEUTICAL FORM**

Shampoo

### **4. PACKAGE SIZE**

250 ml

### **5. TARGET SPECIES**

Dogs

### **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]*

What does this shampoo do?

Armitage Pet Care Insecticidal Flea Shampoo & Conditioner controls fleas on your dog and prevents their return for up to 7 days. To help prevent re-infestation, dog's bedding, basket and regular resting-places such as carpets and soft furnishings should be treated with a suitable insecticide and vacuumed regularly.

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

How do I use this shampoo?

Mix the recommended amount of shampoo with 300ml of lukewarm water. Wet the dog's coat thoroughly with warm water and apply half of the mixture. Massage well into the coat, using fingertips around the head to avoid eyes, ears and mouth. Rinse and repeat with the remainder of the mixture working up to a good lather. Rinse well

with lukewarm water and towel dry. Brush and comb thoroughly. Repeat in 7 days if necessary.

Recommendations:

Use 30ml of shampoo for a small dog (e.g. Terrier)

Use 50ml of shampoo for a medium dog (e.g. Collie).

Use 70ml of shampoo for a large dog (e.g. Alsatian).

For external use only.

## **8. WITHDRAWAL PERIOD**

N/A

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

<User Warnings>

Is this shampoo safe for my dog?

Yes. However, do not use it if your dog is less than 12 weeks old, if your dog is sick, getting over an illness or is feeding puppies. In all of these cases, use a flea comb or speak to your vet. Never use it on cats. Do not use it at the same time as other insecticides.

What precautions should I take to protect my dog?

Do not get shampoo or lather into your dog's eyes, mouth or ears. If signs of disease persist or appear, consult a veterinary surgeon. Do not use more than once a week.

What precautions should I take?

Operator warnings: 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. 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.

Other warnings: Close the bottle and store it upright. Dispose of any waste water onto soil not used for growing vegetables. Dispose of empty packaging and any remaining product in the household refuse.

## **10. EXPIRY DATE**

EXP: end {month/year}

## **11. SPECIAL STORAGE CONDITIONS**

Do not store above 25 °C

Protect from frost. Protect from direct sunlight. Close the bottle, store it upright.

Keep away from food and drink including animal feeding stuffs.

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

Harmful to fish and crustaceans. Do not contaminate aquaria or fish bowls with the product.

Dispose of any waste water onto 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]*

For animal treatment only

AVM-GSL
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## **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**

Distributed by  
Armitage Pet Products Limited  
Colwick  
Nottingham  
NG4 2BA

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

**Vm** <number>

16516/4034

## **17. MANUFACTURER'S BATCH NUMBER**

ManA 16576

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

**Not applicable**

### **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:**

**Not applicable**

**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.]*

**Not applicable**

**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: 17/08/2017**

A handwritten signature in dark ink, appearing to be 'J. J. J. J.', is written below the approval date.