



**Veterinary
Medicines
Directorate**

Veterinary Medicines Directorate

Woodham Lane, New Haw, Addlestone, Surrey KT15 3LS
Telephone (01932) 336911 Fax (01932) 336618
Website: www.gov.uk

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Johnson's Flea & Tick Drops 742mg for Puppies and Small Dogs, cutaneous solution.

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

1 vial containing 742mg of Permethrin 25:75 Cis:Trans in 1ml of solution.

3. PHARMACEUTICAL FORM

Cutaneous solution

4. PACKAGE SIZE

4 or 12 week pack

5. TARGET SPECIES

For smaller dogs and puppies over 8 weeks of age weighing up to 15kg (33lbs)

6. INDICATION(S)

Kills fleas & ticks. 1 treatment protects for up to 4 weeks..

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Twist off cap, holding vial upright. Do not squeeze vial during opening. Part animal's coat between shoulder blades and squeeze entire contents of vial directly onto exposed skin. Squeeze vial firmly during application to ensure all contents are expelled. **DO NOT MASSAGE THE DROPS INTO SKIN. AVOID APPLYING TO FUR.**

The 4 week period of protection may be reduced if coat becomes saturated, e.g. after shampooing, swimming or in heavy rain, also in cases of heavy

infestation, when drops can be safely be re-applied 7 days after initial application. For continued protection, repeat the treatment every 4 weeks. Also treat per bedding and other favourite resting areas.

For external use only

8. WITHDRAWAL PERIOD

Not applicable.

9. SPECIAL WARNING(S), IF NECESSARY

DO NOT USE ON CATS. This product is poisonous to cats. It is important to ensure that cats do not groom the site of application on a dog which has been treated with this product. Seek veterinary advice immediately if this occurs.

Do not use on cats and do not allow cats to lick the site of application on a dog. Do not use on puppies under 8 weeks of age or nursing bitches from which fleas can be removed by careful use of a flea comb. Do not apply drops if other flea and tick control products are being used on dog. Do not use any other flea control products on dog during the 4 week protection period. Do not re-apply drop within 7 days of application. After use, examine site of application periodically as occasionally a sensitive animal may experience localised skin irritation, in which case bathe dog with a mild, non-insecticidal shampoo. If symptoms persist or appear, consult a veterinary surgeon, taking this pack and if possible the vial.

OPERATOR WARNINGS: Avoid the drops coming into contact with your fingers. Wash off any splashes immediately with plenty of clean water. Avoid contact with eyes. In case of accidental eye contact, rinse with clean, fresh water. If eye irritation persists, seek medical advice. Wash hands and exposed skin with soap and water after use. Users making multiple applications, such as in kennels, should wear protective gloves (neoprene or nitrile, 0.3mm minimum thickness). If you feel unwell as a result of handling this product, you should consult your Doctor. Do not handle the area of application for 6 hours following treatment. Treated animals should not be allowed to play or sleep with people, particularly children, for 8 hours immediately following treatment. It is preferable to treat during the evening, when children are in bed. Keep away from food and drink, including animal feedingstuffs.

ENVIRONMENTAL WARNINGS: EXTREMELY DANGEROUS to fish, other aquatic life and reptiles. Do not contaminate aquaria, ponds or other waterways with the product. Treated dogs should not be allowed to swim for at least 12 hours after treatment.

10. EXPIRY DATE

EXP DD/MM/YYYY

11. SPECIAL STORAGE CONDITIONS

Protect from direct sunlight. Do not freeze. Do not refrigerate. Do not store above 25°C. Do not remove vial from packaging until ready to use. Keep container in outer carton.

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

DISPOSAL ADVICE: 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

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 01759/4067

17. MANUFACTURER’S BATCH NUMBER

18. Further information

These drops can be fully effective as part of a programme to eliminate fleas and their larvae from pets and their surroundings. Therefore the animals basket, bedding and regular resting areas such as carpets and soft furnishings should be vacuumed regularly and treated periodically with an insecticide suitable for household use, preferably containing I.G.R. (Insect Growth Regulator) to control flea egg development and help break the flea life cycle. Wash or change pet bedding regularly.

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS {vial}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Johnson's Flea & Tick Drops 742mg for Puppies and Small Dogs, cutaneous solution

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Each 1ml vial contains 742mg Permethrin 25:75 cis:trans

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

Each 1ml vial contains 742mg Permethrin 25:75 cis:trans

4. ROUTE(S) OF ADMINISTRATION

Read instructions and warnings before use.

5. WITHDRAWAL PERIOD

Not Applicable.

6. BATCH NUMBER

xxxx

7. EXPIRY DATE

Exp End mm/yy

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

POISONOUS TO CATS, DO NOT USE ON CATS For External use only, For animal treatment only. Read instructions and Warnings before use.

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.>

<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.>

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”

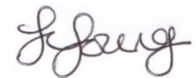
20. MARKETING AUTHORISATION NUMBER(S)

Vm <number>

21. MANUFACTURER’S BATCH NUMBER

<22. OTHER INFORMATION>

Approved: 24/07/2017

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