PARTICULARS TO APPEAR ON <THE OUTER PACKAGE> <AND> <THE IMMEDIATE PACKAGE> {NATURE/TYPE}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Johnson's Cat Flea Powder, Cutaneous Powder.

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Pyrethrins 0.1% w/w (from Pyrethruum Powder 1.3% w/w) and Piperonyl Butoxide 0.8% w/w

3. PHARMACEUTICAL FORM

Cutaneous Powder

4. PACKAGE SIZE

55g

5. TARGET SPECIES

For Cats & Kittens over 12 weeks of age

6. INDICATION(S)

Kills Fleas

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Directions for use: Use when coat is dry, in open air if possible. Apply powder evenly all over body commencing at tail while stroking against lie of coat to ensure that powder reaches the skin. Use 5 – 10g of powder per cat according to size. Avoid eyes, nose and mouth. Brush off excess powder, leave for 30 minutes, then comb or brush thoroughly. Repeat every 3-4 days if necessary, until infestation is cleared. Note: This pack contains sufficient powder to treat a medium sized cat (3-4kg) 8-9 times.

8. WITHDRAWAL PERIOD

Not Applicable

9. SPECIAL WARNING(S), IF NECESSARY

Avoid inhaling the powder. Use in a well-ventilated area.

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, particularly children, until the powder has been brushed out. Keep away from food and drink, including animal feeding stuffs

10. EXPIRY DATE

MM/YY

11. SPECIAL STORAGE CONDITIONS

Do not store above 25ºC.

Store in a dry place.

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

Harmful to fish and crustaceans. Do not contaminate aquaria and fish bowls with the product. Dispose of empty containers 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]*

~~POM-V~~	~~POM-VPS~~	~~NFA-VPS~~	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 Ltd

Sutton Coldfield, West Midlands

B75 7DF

16. MARKETING AUTHORISATION NUMBER(S)

Vm 01759/4038

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.>

<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: 08/08/2017