PARTICULARS TO APPEAR ON Carton

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Johnson's Scaly Lotion, cutaneous solution.

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Contents: Pyrethrum Pale Extract (25%) 0.40% w/v (equivalent to Pyrethrins 0.10% w.v), Piperonyl Butoxide 1.00% w/v.

3. PHARMACEUTICAL FORM

A safe, gentle, soothing lotion.

4. PACKAGE SIZE

15ml

5. TARGET SPECIES

For all Cage Birds, e.g. Budgerigars, Canaries

6. INDICATION(S)

A safe, gentle soothing lotion for treatment of scaly face & scaly leg in cage birds (e.g. Budgerigars, Canaries, etc.) Scaly face and scaly leg are caused by a small mite (Cnemidocptes pilae) which bores into the cere, beak and legs, causing tissue damage unsightly scaly growths & in sever untreated cases, deformities of toes and beak. The infection can spread rapidly to other birds & early treatment is necessary as soon as any symptoms appear.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Directions for use: Apply two to four drops to affected areas, ensuring whole of affected area is treated. A small, clean, dry artists paint brush, or cotton bud, can be used to apply the lotion. Avoid eyes and nostrils. Apply once every two days for a period of 11 days (6 applications). If symptoms reappear, repeat treatment as above. Isolate affected from unaffected birds.

Clean all cages, perches, feed and water containers and other equipment with a disinfectant approved for use in aviaries. If there are other signs of illness or of feather damage, consult a Veterinary Surgeon promptly.

For external use only

8. WITHDRAWAL PERIOD

Not applicable.

9. SPECIAL WARNING(S), IF NECESSARY

Avoid contact with eyes.
If eye contact occurs, rinse with clean, fresh water. Seek medical advice if irritation persists. Wash hands after use.

10. EXPIRY DATE

End mm/yy

11. SPECIAL STORAGE CONDITIONS

Do not store above 25ºC. Protect from frost & direct sunlight. Keep out of reach of children. Keep container in outer carton.

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

Dispose of empty packaging & 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 01759/4050

17. MANUFACTURER'S BATCH NUMBER

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

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Johnson's Scaly Lotion, Cutaneous Solution

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Pyrethrum Pale Extract (25%) 0.40% w/v (equivalent to Pyrethrins 0.10% w/v)
Piperonyl Butoxide 1.00 w/v.

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

15ml

4. INDICATION(S)

A safe, gentle soothing lotion for treatment of scaly face & scaly leg in cage birds (e.g. Budgerigars, Canaries, etc.) Scaly face and scaly leg are caused by a small mite (Cnemidocptes pilae) which bores into the cere, beak and legs, causing tissue damage unsightly scaly growths & in sever untreated cases, deformities of toes and beak. The infection can spread rapidly to other birds & early treatment is necessary as soon as any symptoms appear

5. ROUTE(S) OF ADMINISTRATION

Directions for use: Apply two to four drops to affected areas, ensuring whole of affected area is treated. A small, clean, dry artists paint brush, or cotton bud, can be used to apply the lotion. Avoid eyes and nostrils. Apply once every two days for a period of 11 days (6 applications). If symptoms reappear, repeat treatment as above. Isolate affected from unaffected birds.

Clean all cages, perches, feed and water containers and other equipment with a disinfectant approved for use in aviaries. If there are other signs of illness or of feather damage, consult a Veterinary Surgeon promptly. For external use only

6. WITHDRAWAL PERIOD

Not Applicable.

6. BATCH NUMBER

7. EXPIRY DATE

End mm/yy

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only

9. SPECIAL WARNING(S), IF NECESSARY

Avoid contact with eyes.
If eye contact occurs, rinse with clean, fresh water. Seek medical advice if irritation persists. Wash hands after use.

10. EXPIRY DATE

End mm/yy

11. SPECIAL STORAGE CONDITIONS

Do not store above 25ºC. Protect from frost & direct sunlight. Keep out of reach of children. Keep container in outer carton.

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

Dispose of empty packaging & any remaining product in the household refuse.

13. 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 01759/4050

17. MANUFACTURER'S BATCH NUMBER

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]

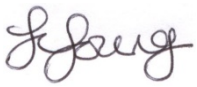
POM-V	POM-VPS	NFA-VPS	AVM-GSL

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