

PARTICULARS TO APPEAR ON THE OUTER PACKAGE (CARTON)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Otodex Veterinary Ear Drops Solution for Dogs and Cats

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Active ingredients

Phenoxyethanol 1.0% w/w

Chlorobutanol hemihydrate 1.1% w/w
in a propylene glycol base.

3. PHARMACEUTICAL FORM

Ear drops solution.

4. PACKAGE SIZE

14 ml

5. TARGET SPECIES

Dogs and cats.

6. INDICATION(S)

For the treatment of ear irritation and otitis externa caused or complicated by infection in dogs and cats.

Clinical trials have demonstrated that Otodex Veterinary Ear Drops are effective in the treatment of the ear mite *Otodectes cynotis* in the dog and cats, although none of the components of Otodex Veterinary Ear Drops has recognised acaricidal activity.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

DO NOT USE IF THE EAR DRUM IS PERFORATED.

Squeeze 3 or 4 drops into the affected ear holding the animal's head still for a few moments to allow thorough penetration of the solution. Repeat daily until conditions clears, usually 4 to 5 days. If necessary, continue use to clear any waxy debris. After healing has taken place check ears at regular intervals for any signs of reinfection and treat as necessary. Do not exceed the recommended dosage. Use each container for only one animal. Discontinue treatment if hypersensitivity occurs.

DO NOT USE IF NECK SEAL IS BROKEN.

8. WITHDRAWAL PERIOD

Not applicable.

9. SPECIAL WARNING(S), IF NECESSARY

For external use only.

If symptoms persist contact your veterinary surgeon.

User Warnings

Avoid contact with skin and eyes. In the event of accidental skin exposure, wash the affected area with soap and water. In the event of accidental eye exposure, flush eye thoroughly with running water. If irritation persists, seek medical advice showing the product label to the doctor. Wash hands after use.

10. EXPIRY DATE

Expiry End:

11. SPECIAL STORAGE CONDITIONS

Do not store above 25°C

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

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 sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Petlife International Limited
Unit 2, Cavendish Road
Bury St Edmunds
Suffolk, IP33 3TE
Tel 01284 761131

16. MARKETING AUTHORISATION NUMBER

Vm 13240/4001

17. MANUFACTURER'S BATCH NUMBER

Batch no.

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE (LABEL)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Otodex Veterinary Ear Drops Solution for Dogs and Cats

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Active ingredients:

Phenoxyethanol 1.0% w/w

Chlorbutanol hemihydrate 1.1% w/w

In a propylene glycol base

3. PHARMACEUTICAL FORM

Ear Drops Solution.

4. PACKAGE SIZE

14 ml

5. TARGET SPECIES

Dogs and cats.

6. INDICATION(S)

For the treatment of ear irritation and otitis externa caused or complicated by infection in dogs and cats.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

DO NOT USE IF THE EAR DRUM IS PERFORATED.

Squeeze 3 or 4 drops into the affected ear daily for 4 to 5 days. Use each container for only one animal. See carton panel for further details. DO NOT USE IF SEAL IS BROKEN.

8. WITHDRAWAL PERIOD

Not applicable

9. SPECIAL WARNING(S), IF NECESSARY

For external use only.

If symptoms persist or appear consult your veterinary surgeon.

Operator warnings

Avoid contact with skin and eyes. In the event of accidental skin exposure, wash the affected area with soap and water. In the event of accidental eye exposure, flush eye thoroughly with running water. If irritation persists, seek medical advice showing the product label to the doctor. Wash hands after use.

10. EXPIRY DATE

EXP.

11. SPECIAL STORAGE CONDITIONS

Keep the container in the outer carton.

Do not store above 25°C.

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

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 the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

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Unit 2, Cavendish Road
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17. MANUFACTURER'S BATCH NUMBER

BATCH

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

PACKAGE LEAFLET FOR:

Not applicable – there is no package leaflet supplied with this product.

Approved: 31 July 2019

A handwritten signature in black ink, appearing to read "J. Muir", with a horizontal line underneath the signature.