

PARTICULARS TO APPEAR ON THE OUTER PACKAGE: {CARTON}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Otodex Skin Cream

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Active ingredients (% w/w)
Chlorocresol 0.50
Phenoxyethanol 0.72
Zinc Oxide 9.00
Lidocaine hydrochloride 0.05

3. PHARMACEUTICAL FORM

Cream

4. PACKAGE SIZE

35 g

5. TARGET SPECIES

For dogs and cats.

6. INDICATION(S)

A soothing aid in the treatment of eczema, sore spots, abrasions and minor burns.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Directions

Clean wound, carefully remove overlying hair from affected parts and lightly apply cream night and morning.

Do not use if tube seal is broken when purchased.

8. WITHDRAWAL PERIOD

Not applicable

9. SPECIAL WARNING(S), IF NECESSARY

For external use only.

Apply sparingly in severe cases.

If symptom persist or appear, consult your veterinary surgeon.

Operator Warnings

Wash hands after use. In the event of accidental eye contact wash immediately with copious amounts of water. If the skin or eye irritation persists – seek medical attention showing the product label to the doctor.

10. EXPIRY DATE

Expiry End:

11. SPECIAL STORAGE CONDITIONS

Do not store above 25°C.
Keep container in outer carton

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 reach and sight of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Petlife International Ltd
Unit 2, Cavendish Road
Bury St Edmunds
Suffolk
IP33 3TE

16. MARKETING AUTHORISATION NUMBER(S)

Vm 13240/4000

17. MANUFACTURER’S BATCH NUMBER

Batch

MINIMUM PARTICULARS TO APPEAR ON THE LABEL WHERE THERE IS NO PACKAGE LEAFLET, E.g. Concertina Labels. {PRINTED TUBE}

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder: Petlife International Limited, Unit 2, Cavendish Road, Bury St Edmunds, Suffolk, IP33 3TE

Manufacturer responsible for batch release: Form Nutrition Limited, Newday House, First Avenue, Cheshire, CW1 6BE, United Kingdom

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Otodex Skin Cream

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENTS

Active ingredients (% w/w)
Chlorocresol 0.50
Phenoxyethanol 0.72
Zinc Oxide 9.00
Lidocaine hydrochloride 0.05

4. PHARMACEUTICAL FORM

Cream

5. PACKAGE SIZE

35 g

6. INDICATION(S)

A soothing aid in the treatment of eczema, sore spots, abrasions and minor burns.

7. CONTRAINDICATIONS

8. ADVERSE REACTIONS

9. TARGET SPECIES

For dogs and cats.

10. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

DIRECTIONS

Clean wound, carefully remove overlying hair from affected parts and lightly apply cream night and morning.

If symptoms persist or appear consult your veterinary surgeon.

11. ADVICE ON CORRECT ADMINISTRATION

APPLY SPARINGLY IN SEVERE CASES.

FOR EXTERNAL USE ONLY.

Invert cap to break the seal. Do not use if tube seal is broken when purchased.

12. WITHDRAWAL PERIOD

13. SPECIAL STORAGE PRECAUTIONS

Keep the container in the outer carton.

Do not store above 25°C.

14. SPECIAL WARNING(S) User Warnings

Wash hands after use. In the event of accidental eye contact wash immediately with copious amounts of water. If the skin or eye irritation persists – seek medical attention showing the product label to the doctor.

15. EXPIRY DATE

Exp. End

16. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

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

17. DATE ON WHICH THE LABEL WAS LAST APPROVED

18. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

[Distribution category]

For animal treatment only.

AVM-GSL

19. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the reach and sight of children.

20. MARKETING AUTHORISATION NUMBER(S)

Vm 13240/4000

21. MANUFACTURER'S BATCH NUMBER

BN

A handwritten signature in black ink, consisting of several vertical strokes followed by a horizontal line that curves upwards and to the right.

Approved 01 November 2018