

**PARTICULARS TO APPEAR ON THE OUTER PACKAGE
PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE**

{Canaural Carton 15 ml, 25 ml and 100 ml}
{Canaural Label 10x15 ml and 100 ml}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

CANAURAL ear drops, suspension for dogs and cats

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

1 g suspension contains:

| | |
|-------------------------|--------------|
| Diethanolamine fusidate | 5.0 mg |
| Framycetin sulphate | 5.0 mg |
| Nystatin | 100,000 I.U. |
| Prednisolone | 2.5 mg |

3. PHARMACEUTICAL FORM

Ear drops, suspension [included in name of product]

4. PACKAGE SIZE

15 ml / 25 ml / 100 ml

5. TARGET SPECIES

For dogs and cats [included in name of product]

6. INDICATION(S)

Read the package leaflet before use.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Shake the bottle well before use.

For auricular use.

For external use only.

Read the package leaflet before use.

8. WITHDRAWAL PERIOD

[Not applicable]

9. SPECIAL WARNING(S), IF NECESSARY

Wash hands after applying the product. See package leaflet for full user warnings.

10. EXPIRY DATE

EXP :{month/year}

Shelf life after first opening the bottle: 3 months.

[ON CARTONS ONLY]

Once opened, use by:
[dd/mm/yyyy]

11. SPECIAL STORAGE CONDITIONS

Do not store above 25°C.

Protect from direct sunlight.

Keep the bottle in the outer carton.

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

Disposal: Read package leaflet

13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

For animal treatment only.

To be supplied only on veterinary prescription.

UK: Vm 24883/4004

POM-V

IE: VPA 10803/003/001

POM

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

Keep out of the reach and sight of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Marketing authorisation holder:
Dechra Veterinary Products A/S
Mekuvej 9
7171 Uldum
Denmark

16. MARKETING AUTHORISATION NUMBER(S)

UK: Vm 24883/4004 [stated in the box together with POM-V and POM]
IE: VPA 10803/3/1 [stated in the box together with POM-V and POM]

17. MANUFACTURER'S BATCH NUMBER

LOT: {number}

ADDITIONAL INFORMATION

[EAN code – ON CARTONS ONLY]
[GTIN code number – ON CARTONS ONLY]
[2D Matrix – ON CARTONS ONLY]
[Dechra logo]
[Pictogram cat and dog]

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

{Canaural - LABEL 15 ml / 25 ml}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

CANAURAL ear drops, suspension for dogs and cats

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

1 g suspension contains:

| | |
|-------------------------|--------------|
| Diethanolamine fusidate | 5.0 mg |
| Framycetin sulphate | 5.0 mg |
| Nystatin | 100,000 I.U. |
| Prednisolone | 2.5 mg |

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

15 ml / 25 ml

4. ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.
Shake the bottle well before use.
For auricular use.
For external use only.

5. WITHDRAWAL PERIOD

[Not applicable]

6. BATCH NUMBER

Lot: {number}

7. EXPIRY DATE

EXP: {month/year}
Shelf life after first opening of the bottle: 3 months.

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

ADDITIONAL INFORMATION

Keep the bottle in the outer carton.
To be supplied only on veterinary prescription.

UK: Vm 24883/4004

POM-V

IE: VPA 10803/003/001

POM

Dechra Veterinary Products A/S
Mekuvej 9
7171 Uldum
Denmark

[Pictogram of dog and cat]
[Dechra logo]

B. PACKAGE LEAFLET

**PACKAGE LEAFLET for
CANAURAL ear drops, suspension for dogs and cats**

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

MARKETING AUTHORITY HOLDER:

Dechra Veterinary Products A/S
Mekuvej 9
7171 Uldum
Denmark

MANUFACTURER RESPONSIBLE FOR THE BATCH RELEASE:

Genera Inc.
Svetonedeljska cesta 2
Kalinovica
10436 Rakov Potok
Croatia

Dales Pharmaceuticals
Snaygill Industrial Estate
Keighley Road, Skipton
North Yorkshire, BD23 2RW
United Kingdom

2. NAME OF THE VETERINARY MEDICINAL PRODUCT:

Canaural ear drops, suspension for dogs and cats.

**3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER
INGREDIENT(S):**

1 g suspension contains:

Active substances:

| | |
|-------------------------|--------------|
| Diethanolamine fusidate | 5.0 mg |
| Framycetin sulphate | 5.0 mg |
| Nystatin | 100,000 I.U. |
| Prednisolone | 2.5 mg |

Excipient:

Sesame oil.
A yellow oily suspension

4. INDICATION(S):

Canaural is effective against the micro-organisms commonly associated with otitis externa including the ear mite, *Otodectes cynotis* and is specifically formulated for the treatment of otitis externa in dogs and cats.

5. CONTRAINDICATIONS:

Do not use in animals with a perforated eardrum.

Do not use concomitantly with products known to be ototoxic.

Do not use in animals with known hypersensitivity to the active substances or to the excipient.

Not recommended for use in pregnant and lactating animals.

6. ADVERSE REACTIONS:

On very rare occasions and primarily in geriatric animals, use of auricular preparations may be associated with hearing impairment which may be either transient or prolonged.

Allergy or hypersensitivity reactions to the active substances or the excipient might occur.

Anti-inflammatory corticosteroids such as prednisolone are known to exert a wide range of side effects. Dosage in medium to long term use should therefore generally be kept to the minimum.

During therapy effective doses suppress the hypothalamic-pituitary-adrenal axis.

Following cessation of treatment symptoms of adrenal insufficiency can arise and this may render the animal unable to deal adequately with stressful situations.

Corticosteroids may delay wound healing and the immunosuppressant actions may weaken resistance to, or exacerbate existing infections.

If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES:

For dogs and cats.

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

Where appropriate, prior to administration, the ear canal and the surrounding area should be cleaned mechanically or by irrigation taking care to avoid further damage to the skin. Any excess exudate, hair or debris should be carefully removed prior to the application of the ear drops. Animal owners should only do this on the direction of the prescribing veterinary surgeon.

Shake the bottle well before use.

Instil 5-10 drops into the ear according to the size of the animal and ear canal twice daily.

Without allowing the animal to shake its head, very gently massage the ear canal after administration holding the pinna in an upright position to ensure penetration of the drops into the ear.

Where ear mite infection is present, consideration should be given to treating both ears, even if infection is apparent in only one. Treatment should continue for at least 3 weeks to ensure that successive generations of ear mites are killed. Animals that are in contact should also be treated.

Where treatment is for a period longer than 7 days regular clinical re-evaluation should be carried out.

Where Gram-negative infections are involved, the use of Canaural should be based on bacterial sensitivity testing. In cases where the treatment period is prolonged, *in vitro* sensitivity should be re-evaluated.

9. ADVICE ON CORRECT ADMINISTRATION:

Official, national and regional antimicrobial policies should be taken into account when the product is used.

Special precautions for use in animals

Following recovery the ears should be checked at regular intervals for any signs of re-infection

Special precautions to be taken by the person administering the veterinary medicinal product to animals

Avoid skin contact with the product.

Wash hands thoroughly after applying the product.

In the case of accidental eye contact, rinse thoroughly with water and seek medical advice.

People with known hypersensitivity to any of the active substances or the excipient should avoid contact with the veterinary medicinal product.

10. WITHDRAWAL PERIOD:

Not applicable.

11. SPECIAL STORAGE PRECAUTIONS:

Keep out of the sight and reach of children.

Do not store above 25°C.

Protect from direct sunlight.

Keep the bottle in the outer carton.

Do not use after the expiry date stated on the label and carton after EXP.

Shelf life after first opening the bottle: 3 months. In order to calculate the date on which any product remaining in the bottle should be discarded add 3 months to the date on which the bottle is opened for the first time. This discard date should be written in the space provided on the carton.

12. SPECIAL WARNING(S):

For animal treatment only.
For external use only.
To be used under veterinary supervision.
Not recommended for use in pregnant and lactating animals.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY:

Dispose of any unused product and empty containers in accordance with guidance from your local waste regulation authority.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED:

July 2019

15. OTHER INFORMATION

LEGAL CATEGORY AND MARKETING AUTHORIZATION NUMBERS:

Veterinary medicinal product authorised for use in UK and IE.
To be supplied only on veterinary prescription.

| | |
|-------------------|-------|
| UK: Vm 24883/4004 | POM-V |
|-------------------|-------|

| | |
|-----------------------|-----|
| IE: VPA 10803/003/001 | POM |
|-----------------------|-----|

PACKAGE QUANTITIES:

Plastic squeeze dropper bottles, supplied in boxes of 1x15 ml, 10x15, 1x25 ml or 1x100 ml.

Not all pack sizes may be marketed.

DISTRIBUTED BY:

For any information about this veterinary medicinal product, please contact the local distributor.

Dechra Veterinary Products Limited
Sansaw Business Park
Hadnall
Shrewsbury
Shropshire
SY4 4AS
United Kingdom

A handwritten signature in black ink, consisting of several loops and a final horizontal stroke.

Approved: 25 July 2019