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Dechra Veterinary Products

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Canaural® Ear Drops, Suspension for Dogs and Cats

Species: Cats, Dogs

Therapeutic indication:Pharmaceuticals: Antimicrobials: Topical preparations: Ear/eye/nose

Active ingredient: Diethanolamine Fusidate, Framycetin Sulfate, Nystatin, Prednisolone

Product: Canaural® Ear Drops, Suspension for Dogs and Cats

Product index: Canaural Ear Drops, Suspension for Dogs and Cats

Incorporating:

Qualitative and quantitative composition

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

Excipients:

Sesame Oil

Pharmaceutical form

Ear drops, suspension.

A yellow oily suspension.

Clinical particulars

Target species

Dogs and cats.

Indications for use

For the treatment of otitis externa including the ear mite, *Otodectes cynotis*, infestation in the dog and cat.

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.

Special warnings

For external use only.

To be used under veterinary supervision.

Special precautions for use

Official, national and regional antimicrobial polices 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 contact with the product.

Wash hands after use.

If the product comes into contact with the eyes, rinse immediately with plenty of water.

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

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 can 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-pituitreal 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.

Use during pregnancy and lactation

The safety of the veterinary medicinal product has not been established during pregnancy and/or lactation.

The use is not recommended during pregnancy and/or lactation.

Amounts to be administered and administration route

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 the veterinary medicinal product should be based on bacterial sensitivity testing. In cases where the treatment period is prolonged, *in vitro* sensitivity should be re-evaluated.

Pharmacological particulars

Pharmacotherapeutic group: Otologicals containing corticosteroids and anti-infectives in combination.

ATCvet code: QS02CA01

Pharmacodynamic properties

The veterinary medicinal product is effective against the micro-organisms commonly associated with otitis externa, including the ear mite, *Otodectes cynotis* and are specifically formulated for the treatment of otitis externa in the dog and cat.

Diethanolamine fusidate: Fusidic acid (present in the veterinary medicinal product as the Diethanolamine salt) is an antibiotic which is highly active against *Staphylococci*, the most

commonly found bacterial pathogen in otitis externa in the dog and cat. Fusidic acid has skin penetrating properties which enhances its antibacterial properties.

Framycetin sulphate: Framycetin sulphate is a broad spectrum antibiotic which has been incorporated for its activity against Gram-negative organisms associated with otitis externa, in particular *Pseudomonas* spp. and *Proteus* spp.

Nystatin: Nystatin is highly active against yeasts. The yeast, *Malassezia pachydermatis* is associated with otitis externa in the dog and cat either by itself or with other organisms.

Prednisolone: Prednisolone is incorporated for its anti-inflammatory and anti-pruritic activity.

All four active ingredients are suspended in oil. A bland oil is used which softens and dissolves ceruminous material and readily penetrates the ear canal. Additionally, the oil used does not matt the hair around the ear, which would prove objectionable to both animal and owner.

Clinical trials have demonstrated that the veterinary medicinal product is effective in the treatment of the ear mite, *Otodectes cynotis,* in the dog and cat. The mode of action is uncertain as none of the components in the veterinary medicinal product have recognised acaricidal activity.

Pharmacokinetic properties

Fusidic acid and Framycetin are not absorbed into the systemic circulation when used topically. In contrast, prednisolone can in some cases be absorbed when used topically.

Excipients

Sesame oil

Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years.

Shelf life after first opening the immediate packaging: 3 months.

Special precautions for storage

Do not store above 25°C.

Protect from direct sunlight.

Keep the bottle in the outer carton.

Immediate packaging

High density polyethylene squeeze dropper bottles, supplied in boxes of 1x15 ml, 10x15 ml, 1x25 ml, 1x100 ml. Not all pack sizes may be marketed.

Disposal

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

Marketing Authorisation Holder (if different from distributor)

Dechra Veterinary Products A/S, Mekuvej 9, DK-7171 Uldum, Denmark

Marketing Authorisation Number

Vm 24883/4004

Significant changes

Date of the first authorisation or date of renewal

24 September 1974

Date of revision of the text

September 2012

Any other information

For animal treatment only. To be supplied only on veterinary prescription. Keep out of the sight and reach of children. For external use only. To be used under veterinary supervision.

Legal category

Legal category:POM-V

GTIN

GTIN description: Canaural Ear Drops, Suspension for Dogs and Cats 15 ml:

GTIN:05701170451931

GTIN description: Canaural Ear Drops, Suspension for Dogs and Cats 25 ml:

GTIN:05701170451948