
Dechra Veterinary Products Limited

(A business unit of Dechra Pharmaceuticals PLC)
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CANAURAL® EAR DROPS, SUSPENSION FOR DOGS AND CATS

Presentation 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.

Ear drops, suspension. A yellow oily suspension.

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

Dosage and 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 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.

Contraindications, warnings, etc 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 precautions for use: 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 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 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-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.

Use during pregnancy and lactation: The safety of the veterinary medicinal product has not been estab-

lished during pregnancy and/or lactation. Use is not recommended during pregnancy and/or lactation.

Interactions: None known.

Incompatibilities: None known.

Pharmaceutical precautions 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 of the veterinary medicinal product as packaged for sale: 2 years.

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

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

Legal category POM-V

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

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

Manufacturer responsible for the batch release: Dales Pharmaceuticals, Snaygill Industrial Estate, Keighley Road, Skipton, North Yorkshire, BD23 2RW.

Date of last review: September 2012

Marketing authorisation holder (if different from distributor) Dechra Veterinary Products A/S, Mekuvej 9, DK-7171 Ulrum, Denmark.

Marketing authorisation number Vm 24883/4004

GTIN (Global Trade Item No)

Canaural Ear Drops, Suspension for Dogs and Cats
15 ml: 05701170156768

Canaural Ear Drops, Suspension for Dogs and Cats
25 ml: 05701170001273

Requested by: lynne.easton@dechra.com

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Approved datasheets found: 1

Approved for book but not on website: 0

Datasheets marked as draft (ignored): 0

Directory of participants

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List of Products by Therapeutic Indication

PHARMACEUTICALS

Antimicrobials

Topical preparations

Ear/eye/nose

Canaural Ear Drops, Suspension for Dogs
and Cats 1

List of Products by Species

Please note that a species in brackets after a product name may not necessarily be a part of that product name but is intended to make the index easier to use.

Cats

Canaural Ear Drops, Suspension for Dogs and
Cats 1

Dogs

Canaural Ear Drops, Suspension for Dogs and
Cats 1

List of Products by Active Ingredients

This index of non-proprietary names (active ingredients) is provided to enable users of the Compendium to identify the brand names of relevant products when only the non-proprietary names are known.

It should be noted that although different products may contain the same active ingredient this does not imply that they are equivalent in regard to bioavailability or therapeutic activity.

Some products contain a number of ingredients and it has not been possible in every instance to identify such products by a reference in this index to each ingredient.

Key

Non-proprietary name in bold type. Proprietary name in ordinary type.

Diethanolamine Fusidate

Canaural Ear Drops, Suspension for Dogs and
Cats 1

Framycetin Sulfate

Canaural Ear Drops, Suspension for Dogs and
Cats 1

Nystatin

Canaural Ear Drops, Suspension for Dogs and
Cats 1

Prednisolone

Canaural Ear Drops, Suspension for Dogs and
Cats 1

Alphabetical Index of Products

Canaural Ear Drops, Suspension
for Dogs and Cats 1

ALPHABETICAL