

# Canaural Ear Drops

## Introduction



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## Presentation

A yellow oily suspension. Each gram contains:

Diethanolamine fusidate BPC 1968	5 mg
Framycetin sulphate PhEur	5 mg
Nystatin PhEur	100,000 units
Prednisolone PhEur	2.5 mg

## Uses

Canaural Ear Drops are 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.

Fusidic acid (present in Canaural 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 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 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.

Clinical trials have demonstrated that Canaural 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 Canaural have recognised acaricidal activity.

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.

## 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 before using.

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.

## Contra-indications, warnings, etc

For animal treatment only.

To be used under veterinary supervision.

For external use only.

Do not use in animals with a perforated eardrum.

Do not use concomitantly with products known to be ototoxic.

Not recommended for use in pregnant animals.

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 hypothalamo-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.

Cats may react with ataxia, nystagmus, or deafness if the tympanum is perforated.

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

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

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

During a course of treatment the situation should be reviewed frequently by close veterinary supervision.

Certain individuals have had skin irritancy/contact allergies from using similar products. Avoid using this product if you have a known sensitivity to either this product or any of the ingredients used in this product.

Avoid skin contact with this product and wash hands thoroughly after applying.

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

## Pharmaceutical precautions

Do not store above 25°C. Protect from light.

Following first opening use the product within 3 months. Discard unused product.

Dispose of empty containers in the domestic refuse. Return any unused product to the veterinary surgery or local pharmacy.

Unused product and containers should be disposed of in accordance with any guidance from an appropriate waste regulation authority.

Keep out of the reach of children.

## Legal category

POM-V

## Packaging Quantities

High density polyethylene squeeze dropper bottles, supplied in boxes of 1 × 15 ml, 1 × 25 ml or 1 × 100 ml.

## Further information

Nil

## Marketing authorisation number

Vm 24883/4004.