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Date: Friday, February 20, 2026 10:24

Virbac Limited

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Easotic ear drops, suspension for dogs

Species: Dogs

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

Active ingredient: Gentamicin Sulfate, Hydrocortisone Aceponate, Miconazole Nitrate

Product: EasOtic

Product index: EasOtic

Incorporating:

Presentation

Ear drops suspension for dogs containing:

Hydrocortisone aceponate 1.11mg/mL

Miconazole as nitrate 15.1mg/mL

Gentamicin as sulfate 1505IU/mL

Excipients: Liquid paraffin.

Uses

Target Species

Dogs

Indications for use

Treatment of acute otitis externa and acute exacerbation of recurrent otitis externa associated with bacteria susceptible to gentamicin and fungi susceptible to miconazole in particular *Malassezia pachydermatis*.

Contraindications

Do not use in cases of hypersensitivity to the active substances or to any of the excipients, to corticosteroids, to other azole antifungal agents and to other aminoglycosides. Do not use if the

eardrum is perforated. Do not use concurrently with substances known to cause ototoxicity. Do not use in dogs with generalised demodecosis.

Dosage and administration

Auricular use.

One mL contains 1.11mg hydrocortisone aceponate, 15.1mg miconazole (as nitrate) and 1505 IU gentamicin (as sulfate).

It is recommended that the external ear canal should be cleaned and dried before treatment and excess hair around the treatment area be cut.

Shake the bottle thoroughly before first administration and prime the pump.

The recommended dosage is 1mL of the veterinary medicinal product per ear once a day for five consecutive days.

Introduce the atraumatic canula in the ear canal. Administer one dose (1mL) of the product in each affected ear. This dose is adequately delivered by one pump activation. The airless pump allows the product to be administered whatever the position of the bottle is.

After application, the base of the ear may be massaged briefly and gently to allow the preparation to penetrate to the lower part of the of the ear canal. The product as presented allows treating a dog suffering from bilateral otitis. The veterinary medicinal product should be used at room temperature (i.e. do not instil cold product).

Contra-indications, warnings, etc

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Do not use in cases of hypersensitivity to the active substances or to any of the excipients, to corticosteroids, to other azole antifungal agents and to other aminoglycosides.

Do not use if the eardrum is perforated.

Do not use concurrently with substances known to cause ototoxicity.

Do not use in dogs with generalised demodecosis.

Special warnings

Bacterial and fungal otitis is often secondary in nature and appropriate diagnosis should be used to determine the primary factors involved.

Special precautions for use

Special precautions for use in animals

If hypersensitivity to any of the components occurs, treatment should be discontinued and appropriate therapy instituted. Use of the veterinary medicinal product should be based on

identification of infecting organisms and susceptibility testing and take into account official and local antimicrobial policies.

Use of the veterinary medicinal product deviating from the instructions given in the SPC may increase the prevalence of bacteria and fungi resistant to gentamicin and miconazole respectively and may decrease the effectiveness of treatment with aminoglycosides and azole antifungal agents, due to the potential for cross-resistance.

In case of parasitic otitis, an appropriate acaricidal treatment should be implemented. Before the veterinary medicinal product is applied, the external auditory canal must be examined thoroughly to ensure that the ear drum is not perforated in order to avoid the risk of transmission of the infection to the middle ear and to prevent damage to the cochlear and vestibular apparatus.

Gentamicin is known to be associated with ototoxicity when administered by the systemic route at higher doses.

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

In case of accidental skin contact, it is recommended to wash thoroughly with water.

Avoid contact with eyes. In case of accidental contact, rinse with abundant quantities of water. In case of eye irritation, seek medical advice. In case of accidental ingestion, seek medical advice immediately and show the package leaflet or the label to the physician.

Adverse reactions (frequency and seriousness)

Mild to moderate redness of the ear was common (2.4% of treated dogs). Papules were observed uncommonly (less than 1% of treated dogs). In all cases, treatment with the veterinary medicinal product was not discontinued and all dogs recovered without any specific therapy. In very rare cases, the use of the veterinary medicinal product has been associated with hearing impairment (partial hearing loss or deafness), primarily in geriatric dogs. Based on post-marketing safety experience, hearing improvement was observed in most dogs with deafness/loss of hearing and complete recovery was confirmed in 70% of cases with an adequate follow-up.

Among dogs with full recovery, improvement has been rapidly seen. Recovery has been observed as early as one week after onset of signs, the majority of dogs recovering within one month; in a minority of reports, the deafness lasted for up to two months.

If deafness or partial hearing loss occurs, treatment should be stopped. In very rare cases, type-I hypersensitivity reactions (facial swelling, allergic pruritus) have been observed. If this occurs, treatment should be stopped.

The frequency of adverse reactions is defined using the following convention:

- very common (more than 1 in 10 animals treated displaying adverse reaction(s))

- common (more than 1 but less than 10 animals in 100 animals treated)

- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)

- rare (more than 1 but less than 10 animals in 10,000 animals treated)

- very rare (less than 1 animal in 10,000 animals treated, including isolated reports.

Use during pregnancy, lactation or lay

The safety of the veterinary medicinal product has not been established during pregnancy and lactation. Systemic absorption of hydrocortisone aceponate, gentamicin sulphate and miconazole nitrate being negligible, it is unlikely for teratogenic, foetotoxic or maternotoxic effects to occur at the recommended dosage in dogs. Use only accordingly to the benefit-risk assessment by the responsible veterinarian.

Interaction with other medicinal products and other forms of interaction

Compatibility with ear cleaners has not been demonstrated.

Overdose (symptoms, emergency procedures, antidotes), if necessary

At 3 and 5 times the recommended dose, no local or general adverse reactions were observed with the exception of some dogs showing erythema and papulae in the ear canal.

In dogs treated at the therapeutic dose for ten consecutive days, serum cortisol levels decreased from five days onward and returned to normal values within ten days after the end of treatment. However, serum cortisol response levels post ACTH stimulation remained in the normal range during the extended treatment period, indicating a preserved adrenal function.

Pharmaceutical precautions

Keep out of the sight and reach of children. This medicinal veterinary product does not require any special storage conditions. Do not use after the expiry date stated on the label. Once open use within 10 days.

Major incompatibilities

Do not mix with any other veterinary medicinal product.

Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 18 months.

Shelf life after first opening the immediate packaging: 10 days.

Special precautions for storage

Do not store above 25°C.

Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

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

Legal category:POM-V

Packaging quantities

Box containing 1 multidose container (the content of 10mL is equivalent to 10 doses).

Multi-dose container composed of two extruded parts, one external white polypropylene rigid tube and one internal (ethylene-methacrylic acid)-zinc copolymer (Surlyn) flexible pouch containing a steel ball, closed with a 1 ml dosing airless pump equipped with a flexible atraumatic cannula and covered by a plastic cap.

Further information

Pharmacodynamic properties

The veterinary medicinal product is a fixed combination of three active substances (corticosteroid, antifungal and antibiotic):

Hydrocortisone aceponate belongs to the diester class of the glucocorticosteroids with a potent intrinsic glucocorticoid activity which means a relief of both inflammation and pruritus leading to an improvement of clinical signs observed in otitis externa. Miconazole nitrate is a synthetic imidazole derivative with a pronounced antifungal activity.

Miconazole selectively inhibits the synthesis of ergosterol, which is an essential component of the membrane of yeasts and fungi including *Malassezia pachydermatis*. Mechanisms of resistance to azoles consist of either failure in antifungal accumulation or modification of target enzyme. No standardised *in-vitro* susceptibility breakpoints have been defined for miconazole; however, using the method by Diagnostics Pasteur, no resistant strains were found.

Gentamicin sulphate is an aminoglycoside bactericidal antibiotic which acts by inhibiting protein synthesis. Its spectrum of activity includes Gram-positive and Gram-negative bacteria, such as the following pathogenic organisms isolated from the ears of dogs: *Staphylococcus intermedius, Pseudomonas aeruginosa, Proteus mirabilis, Escherichia coli,* etc.

Since many bacterial strains may be involved in otitis externa in dogs, the mechanisms of resistance can vary. The bacterial resistance phenotypes to gentamicin are mainly based on three mechanisms: enzymatic modification of aminoglycosides, failure of intracellular penetration of the active substance and alteration of the aminoglycoside target. Cross-resistance is mainly linked with efflux pumps which confer resistance to β-lactams, quinolones and tetracyclines depending on the specificity of the pump with its substrate. Co-resistance has been described, i.e. gentamicin resistance genes are found to be physically linked to other antimicrobial resistance genes that are transferred between pathogens due to transferable genetic elements such as plasmids, integrons and transposons. Gentamicin resistant bacteria isolated from the field between 2008 and 2010 in

canine otitis before treatment (determined according to CLSI guideline breakpoint ≥ 8 for all isolates except for *Staphylococci* ≥ 16 µg/ml) were low: 4.7%, 2.9% and 12.5% for *Staphylococcus spp., Pseudomonas* and *Proteus spp*. respectively. All *Escherichia coli* isolates were fully susceptible to gentamicin.

Pharmacokinetic particulars

After application of the veterinary medicinal product into the ear canal, absorption of miconazole and gentamicin through the skin is negligible.

Hydrocortisone aceponate belongs to the diesters' class of glucocorticosteroids. The diesters are lipophilic components ensuring an enhanced penetration into the skin associated with low systemic bioavailability. The diesters are transformed inside the skin structures in C17 monoesters responsible for the potency of the therapeutic class. In laboratory animals, hydrocortisone aceponate is eliminated the same way as hydrocortisone (other name for endogenous cortisol) through urine and faeces.

Marketing Authorisation Number

MARKETING AUTHORISATION HOLDER

VIRBAC

1ère avenue

2065 m LID

06516 Carros

FRANCE

Vm 05653/5002

Northern Ireland: EU/2/08/085/001

Significant changes

GTIN

GTIN description: Easotic 10ml

GTIN:3597133047806