PARTICULARS TO APPEAR ON THE OUTER PACKAGE

BOX OF 1 MULTI-DOSE CONTAINER OF 10 DOSES

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Easotic ear drops, suspension

2. STATEMENT OF ACTIVE SUBSTANCES

Hydrocortisone aceponate 1.11 mg/ml,
Miconazole as nitrate 15.1 mg/ml,
Gentamicin as sulphate 1,505 IU/ml.

3. PACKAGE SIZE

10 ml (10 doses).

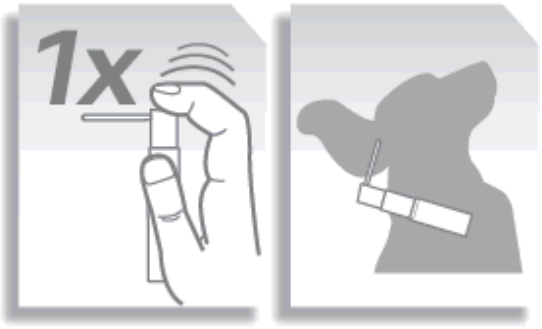
4. TARGET SPECIES

Dogs.

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

For auricular use only.



7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp. {mm/yyyy}
Once opened use within 10 days.

9. SPECIAL STORAGE PRECAUTIONS

Do not store above 25°C.

10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”

Read the package leaflet before use.

11. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

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

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

VIRBAC

14. MARKETING AUTHORISATION NUMBERS

Vm 05653/5002

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

MULTI-DOSE CONTAINER

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Easotic

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

10 ml

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Easotic ear drops, suspension for dogs - Multidose

2. Composition

Hydrocortisone aceponate 1.11 mg/ml,
Miconazole as nitrate 15.1 mg/ml,
Gentamicin as sulphate 1,505 IU/ml.

A white suspension.

3. Target species

Dogs.

4. 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*.

5. Contraindications

Do not use in case 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.

6. Special warnings

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 safe use in the target species:
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 summary of product characteristics 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.

Pregnancy and lactation:
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:
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.

Major incompatibilities:
Do not mix with other veterinary medicinal products.

7. Adverse events

Dogs:

Common (1 to 10 animals / 100 animals treated):
Application site reddening (ear) [1,2]
Uncommon (1 to 10 animals / 1,000 animals treated):

Application site papule [2]
Very rare (<1 animal / 10,000 animals treated, including isolated reports):
Application site inflammation Impaired Hearing [3,4], Deafness [3,4] Hypersensitivity reactions (facial swelling, allergic pruritus) [4]

[1] Mild to moderate.
[2] Recovering without specific therapy.
[3] Primarily in geriatric dogs.
Complete recovery was confirmed in 70% of post marketing cases with an adequate follow-up, otherwise hearing improvement was observed in most dogs.
Recovery has been observed between one week and up to two months after onset of signs.
[4] If the adverse reaction occurs, treatment should be stopped.

Reporting adverse events is important. It allows continuous safety monitoring of a product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder or the local representative of the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system at:

Website:
https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine

e-mail: adverse.events@vmd.gov.uk

8. Dosage for each species, routes and method of administration

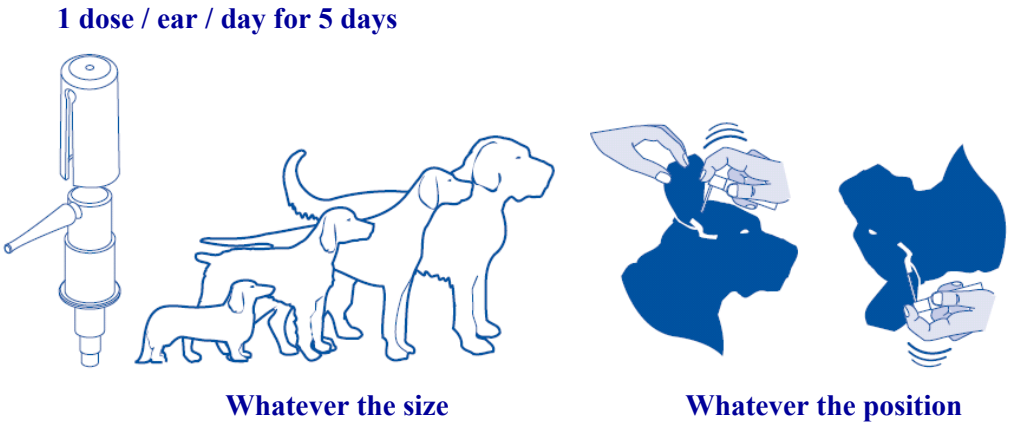
Auricular use.
One ml contains 1.11 mg hydrocortisone aceponate, 15.1 mg miconazole (as nitrate) and 1,505 IU gentamicin (as sulphate).
It is recommended that the external ear canal should be cleaned and dried before treatment and excess hair around the treatment area be cut.

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

[Multi-dose container:]
Shake the bottle thoroughly before first administration and prime the pump by pressing it.

Introduce the atraumatic canula in the ear canal. Administer one dose (1 ml) 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.



The product as presented allows treating a dog suffering from bilateral otitis.

[Single-dose container:]
To administer one dose (1 ml) of the product in the affected ear:
- Take out one pipette from the box. Shake the pipette thoroughly before use.
- To open: hold up the pipette upright and break the top of the cannula.
- Introduce the atraumatic cannula in the ear canal. Squeeze gently but firmly in the middle of the body of the pipette.

9. Advice on correct administration

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 ear canal.
The veterinary medicinal product should be used at room temperature (i.e. do not instil cold product).

10. Withdrawal periods

Not applicable.

11. Special storage precautions

Keep out of the sight and reach of children.
Do not store above 25 °C.
Do not use this veterinary medicinal product after the expiry date, which is stated on the label.
Shelf life after first opening the multi-dose container: 10 days.

12. Special precautions for disposal

Medicines should not be disposed of via wastewater.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any applicable national collection systems. These measures should help to protect the environment.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

Vm 05653/5002

Box containing 1 multi-dose container (the content of 10 ml is equivalent to 10 doses).
Cardboard box containing 5, 10, 50, 100 or 200 pipettes.

Not all pack sizes may be marketed.

15. PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

16. Contact details

Marketing authorisation holder and manufacturer responsible for batch release:
VIRBAC
1ère avenue 2065m LID
06516 Carros
France

Local representatives and contact details to report suspected adverse reactions:
Virbac Ltd,
Suffolk, IP 30 9UP-UK
Tel: +44(0)-1359 243243

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

17. Other information

POM-V

Approved 16 September 2026
Gavin Hall