

Veterinary medicine package leaflet

This medicine is supplied on veterinary prescription only
For use in animals only

1) Name, form, and strength of the veterinary medicine:

Easotic Veterinary

Ear drops (as suspension)

2) Name and quantity of active ingredients in a unit dose:

Name and quantity of active ingredients in each 1 ml of suspension:

Hydrocortisone aceponate 1.11 mg/ml

Gentamycin (as sulfate) 1,505 IU/ml

Miconazole (as nitrate) 15.1 mg/ml

For the list of inactive ingredients and allergens in this medicine, see section 13.

Read the entire leaflet carefully before you start using this medicine.

This leaflet contains concise information about this medicine. If you have any further questions, consult your veterinarian or pharmacist.

3) What is this medicine intended for?

This medicine is intended for treating dogs with an acute external ear inflammation and worsening of a recurrent external ear inflammation, caused by bacteria that are sensitive to the antibiotic gentamycin, and by fungi that are sensitive to the substance miconazole, particularly *Malassezia pachydermatis*.

Therapeutic group:

- Hydrocortisone aceponate is a glucocorticosteroid. It has anti-inflammatory activity.
- Gentamycin sulfate is an aminoglycoside; it has antibiotic activity against gram-positive and gram-negative bacteria.
- Miconazole nitrate is a synthetic imidazole derivative. It has antifungal activity.

4) Contraindications:

Do not use this medicine:

- if your dog is sensitive (allergic) to the active ingredients or to the other ingredient that this medicine contains. Active ingredients are listed in Section 1 and the additional ingredient is listed in Section 13.
- if your dog is sensitive (allergic) to corticosteroids, azole antifungals and/or aminoglycoside antibiotics.
- if there is a tear or hole in the ear drum.
- If your dog has been infected with demodecosis (small parasites that live in dogs' fur and/or ear).

5) Side effects:

Like all medicines, using this medicine can cause side effects in some dogs. Do not be alarmed by this list of side effects. Your dog may not experience any of them.

Common side effects (appear in 1-10 dogs out of 100): slight to medium redness in the ear (observed in 2.4% of treated dogs). The effect cleared up on its own, and there was no need to stop treatment.

Uncommon side effects (appear in 1-10 dogs out of 1,000): small sores / lump in the ear (observed in less than 1% of treated dogs). The effect cleared up on its own, and there was no need to stop treatment.

Very rare side effects (appear in less than one dog out of 10,000): hearing loss (partial or complete), usually this is temporary, and mostly in old dogs. Stop treatment and contact your veterinarian.

Signs of hypersensitivity (allergy) to the medicine, visible as swelling in the face and itching. Stop treatment and contact your veterinarian.

If any side effect gets worse, or if your dog experiences a side effect not mentioned in this leaflet, consult your veterinarian.

You can report side effects to the Ministry of Health by following the link 'Reporting Side Effects of Medication' on the Ministry of Health home page (www.health.gov.il) which links to an online form for reporting side effects, or by following this link: <https://sideeffects.health.gov.il/>

6) Target animals:

This medicine is intended for use in dogs only.

7) Route of administration and dosage in the target animal:

Always use according to the veterinarian's instructions. Check with your veterinarian or pharmacist if you are not sure. Only your veterinarian will determine your animal's dose and how to take this medicine.

Do not exceed the recommended dose.

Route of administration: Ear drops in suspension form, inserted into the ear using a specialized atomizer.

Dose: The recommended dose is 1 ml of drops in each ear that needs treatment, once a day for 5 consecutive days.

This dosage is correct for all dogs regardless of age, weight, breed, and gender.

Persist with the treatment as recommended by your veterinarian.

This bottle contains 10 ml of ear drops, which is enough for a complete course of treatment in both ears for 5 days.

Frequency of administration: Treat the ear once a day for 5 consecutive days.

If you stop giving your dog this medicine: Even if your dog's health improves, do not stop treatment with this medicine without consulting your veterinarian.

Do not give medicines in the dark! Check the label and dose each time you give your dog this medicine. Wear glasses if you need them. If you have any further questions about using this medicine, consult your veterinarian or the pharmacist.

8) How to use this medicine:

- It is advisable to clean and dry the ears before administering the drops.
- If your dog has long or excessive hair in the treated area, it is advisable to cut it before you start treating the dog.
- How to use the bottle: **Shake the bottle well before you use it for the first time.**
- It is important that the bottle is at room temperature when you apply the drops (do not apply cold drops that have been kept in the refrigerator).
- Carefully place the atomizer in the ear canal. Press the actuator once to spray a measured dose of 1 ml into the ear.
- If necessary, repeat the same instructions in the other ear.
- To make it easier to insert the atomizer into the ear, you may hold the bottle at any angle. The bottle does not contain any air so the drops exit the bottle regardless of the angle in which the bottle is held.
- After applying the drops, it is advisable to gently massage the base of your dog's ear on the outside (for a short while) to help the drops penetrate into the lower part of the ear canal.
- Wash hands after applying this medicine.

9) Withdrawal period:

Withdrawal period prior to sacrifice: Not applicable. This medicine is intended for dogs only.

10) Warnings:

- **Special warnings about the safety of using this medicine in animals:** Occasionally, a bacterial and/or fungal ear inflammation is caused by some other primary cause. It is important to discover what the primary cause of the problem is, and treat it.
- If the middle ear inflammation is caused by external parasites, consult your veterinarian about treating your dog for the external parasites.
- Using this medicine must be based on identification of the infection agent and a sensitivity test.
- Failing to follow the instructions for using this medicine may cause resistance of the bacteria and fungi to the active ingredients, and it may also reduce the efficacy of aminoglycosides and other azoles due to potential cross-resistance.

- Before administering this medicine, to avoid transmitting the infection to the middle ear and damaging the ear, examine the outer ear canal carefully to ensure there is no perforation of the ear drum.
- Gentamycin is known to be toxic to the ear (ototoxic) when given systemically in large doses.
- **Special safety precautions for the person administering the medicine.** Put the bottle back in the carton after using this medicine. Wash your hands after using this medicine.
- Avoid contact of the ear drops with the skin of the person administering the treatment. In case of contact, rinse thoroughly with running water.
- Avoid contact with the eyes of the person administering the treatment. In case of contact with eyes, rinse thoroughly with plenty of running water. If there is irritation in the eye, consult your doctor.
- If a person accidentally swallows some of this medicine, particularly if this is a child, immediately see a doctor or go to a hospital emergency room and bring the medicine package with you.
- **Gestation and lactation:** If your dog is gestating or lactating, consult your veterinarian before using this medicine.
- When given in the ear at the recommended dose, the amount of the active ingredients hydrocortisone aceponate, gentamycin sulfate, and miconazole nitrate absorbed in the blood is negligible and is not expected to be dangerous to the fetus, no birth defects are expected, and no danger is expected to the gestating bitch.
- Safety of this medicine in gestating and lactating bitches has not been tested. Your veterinarian will weigh the risk against the benefit of using this medicine in these cases.
- **Drug interactions and other interactions:** Avoid using this medicine together with other medicines that are known to be toxic to ears (ototoxic drugs).
- Using this medicine with ear-cleaning products has not been tested.
- **Overdose:** In overdoses of 3 to 5 times the required dose, no localized or general side effects were observed except for slight redness or small sores / lump in the ear canal.
- Dogs who were treated for 10 consecutive days had decreased blood cortisol levels starting on the fifth day and normal values returned within 10 days of stopping the medicine.
- **Incompatibility:** Do not mix this medicine with other medicines and/or products.

11) Storage instructions:

- Prevent poisoning! To prevent poisoning, keep this, and all other medicines, in a closed place out of reach of children and/or infants.
- Do not use the medicine after the expiry date (exp. date) stated on the package. The expiry date refers to the last day of that month.
- **Storage conditions:** Store below 25°C.
- **Shelf-life after first opening:** 10 days.

12) Instructions for destroying the medicine / any remaining medicine after use:

- Do not throw away medicines in the toilet or with household waste.

- Ask your pharmacist or your veterinarian how to dispose of expired medicines or medicines that you no longer need. These measures will help protect the environment.

13) Additional information:

- **In addition to the active ingredients, this medicine also contains the following inactive ingredient:** liquid paraffin.
- **What the medicine looks like and what the package contains:** The medicine is a white suspension.
- The suspension is packaged in a bottle with atomizer, inside a carton.
- **Pack size:** This medicine is supplied as follows:
- A capped bottle with atomizer. Each bottle contains 10 ml suspension. Cartons contain 1, 2, 3, 4, or 5 bottles.
- The number of bottles in the package is listed on the carton.
- Not all packages may be available.
- **Registration holder:** Vetmarket Ltd., 23 HaChoresh Rd., Industrial Park Modi'in District
- **Manufacturer:** Virbac, Carros, France.

This medicine is intended for male and female dogs.

Registration number of the medicine in the Ministry of Health National Drug Registry:
159.84.34886.00

Revised in December 2021 in accordance with the instructions of the Ministry of Health.