

ULTRAFIL® PLUS Otic Suspension

ANTI-INFLAMMATORY - ACARICIDE - ANTIFUNGAL - ANTIBACTERIAL



ULTRAFIL® PLUS, otic suspension, is indicated in the treatment of external otitis caused by bacteria, fungi and / or mites sensitive to the association. Its use is especially indicated in ear infections caused by bacteria such as, *Staphylococcus spp.*, *Streptococcus spp.*, *Pseudomona aeruginosa*, *Proteus spp.* and *Escherichia coli*; fungi such as, *Malassezia pachydermatis*, *Candida spp.* and *Microsporum canis*, and / or mites of the *Otodectes cynotis* species.

Technical Specification

SPECIES

Dogs and cats.

DOSAGE FORM

Otic Suspension

THERAPEUTIC ACTION

Anti-inflammatory - Acaricide - Antifungal - Antibacterial

COMPOSITION

Each mL of suspension contains:

Gentamicin Sulfate	5.09 mg
(Equivalent to 3.0 mg of Gentamicin base)	
Betamethasone Dipropionate	1.29 mg
(Equivalent to 1.0 mg of Betamethasone base)	
Clotrimazole	10 mg
Thiabendazole	40 mg
Excipients q.s.p	1 mL

PROPERTIES

ULTRAFIL® PLUS is a pharmacological association of gentamicin, clotrimazole, betamethasone and thiabendazole, which give it antibacterial, antifungal, anti-inflammatory and acaricidal properties.

Gentamicin is a bactericidal aminoglycoside antibiotic with good activity against a variety of bacteria, especially gram-negative aerobic bacilli. Gentamicin works by inhibiting normal protein synthesis in susceptible bacteria. Specifically, gentamicin is active against organisms commonly isolated in cases of otitis, such as: *Staphylococcus spp.*, *Streptococcus spp.*, *Pseudomona aeruginosa*, *Proteus spp.*, And *Escherichia coli*, among others.

Clotrimazole is an imidazole antifungal agent, which is used in the treatment of infections caused by various species of pathogenic dermatophytes, fungi and *Malassezia* sp. Its action affects the synthesis of essential components of the fungal plasma membrane, consequently affecting their growth and division. In vitro studies have shown its activity against *Candida* spp., *Trichophyton rubrum*, *Trichophyton mentagrophytes*, *Microsporum canis* and *Malassezia pachydermatis*.

Betamethasone is a long-acting synthetic glucocorticoid. It has an anti-inflammatory potency 25 times more powerful than hydrocortisone, and it does not have mineralocorticoid activity. Its action decreases or prevents tissue responses to inflammatory processes in such a way that they reduce the symptoms of inflammation without affecting the basal cause.

Thiabendazole is a benzimidazole agent, with antiparasitic, antifungal and acaricidal activity. Its action occurs through the inhibition of the enzyme fumarate reductase, blocking mitochondrial function, generating an inability to obtain energy, and causing the death of the parasite. Furthermore, it is described that benzimidazoles generally bind to beta-tubulin, blocking tubulin polymerization to microtubules, consequently damaging the integrity and transport functions of parasitic cells. Studies have proven its excellent activity against the *Otodectes cynotis* mite in cases of otitis in dogs and cats.

INDICATIONS

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ROUTE OF ADMINISTRATION AND DOSAGE

Topical administration by instillation into the external ear canal.

How to use and dosage:

- Shake before using.
- Clean and dry the external ear canal before applying the product.
- Remove all foreign material such as exudate, cell debris, etc.
- Trim excess hair from the area to be treated.
- Verify the integrity of the tympanic membrane.
- Instill 3 to 5 drops of Ultrafil® Plus into the ear canal to be treated, once a day, for 7 consecutive days.

CONTRAINDICATIONS

- ULTRAFIL® PLUS is contraindicated in patients with hypersensitivity to any of its components.
- Do not use in patients with tympanic perforation.
- Do not use in conjunction with drugs that can induce ototoxicity.
- Do not administer during pregnancy and lactation.
- Do not administer in breeding animals.

SPECIAL PRECAUTIONS FOR USE

- Before starting treatment, identification of the etiologic agent (s) should be carried out, either by smear or culture. Furthermore, the antibiotic susceptibility of pathogenic bacteria should be evaluated before using this preparation.
- Before instilling any medication into the ear, examine the external ear canal to ensure there is no rupture of the tympanic membrane, in order to avoid contamination of the middle ear, as well as vestibular and cochlear injuries.
- The Dachshund breed may be particularly sensitive to treatment with Thiabendazole.

SPECIAL PRECAUTIONS FOR THE OPERATOR

- Wash hands after administering the product.
- If the product comes into contact with the eyes, wash with plenty of water
- In case of accidental ingestion do not induce vomiting. Get immediate medical help.

WARNINGS

Keep out of the reach of children.

ADVERSE EFFECTS

- Using ULTRAFIL® PLUS for more than 7 days may delay wound healing.
- The use of ULTRAFIL® PLUS may be associated with deafness or partial hearing loss in a small number of sensitive (geriatric) dogs. Hearing deficit is usually temporary. If vestibular or hearing dysfunctions are detected during the course of treatment, therapy should be discontinued and a flushing of the external ear canal should be performed.

OBSERVATIONS

External use only.

SECURITY

Clinical studies and safety studies of otic suspensions formulated with these compounds provide a wide margin of safety according to the recommended dose level. In cases of massive applications, patients may present symptoms associated with overdoses of each of its components, such as:

Gentamicin: When absorbed systemically it has the potential to cause nephrotoxicosis, neurotoxicosis, and ototoxicosis.

Betamethasone: Its brief administration, even in massive doses, does not usually cause harmful effects. Its chronic use can cause symptoms of hyperadrenocorticism such as polydipsia, polyuria, weight gain, sodium retention, potassium loss, etc.

Clotrimazole: It is unlikely that there will be signs of an overdose caused by clotrimazole since it is poorly absorbed after its dermal application.

Thiabendazole: A modest overdose is unlikely to cause significant problems. In dogs it has been seen that high and chronic doses could cause signs such as vomiting, diarrhea, alopecia and lethargy.

Precautions for disposing of unused product or waste material:

Do not remove empty containers or product residues on the ground or water courses. Discard the remains of unused product in its original container. Dispose of this product with caution with household waste.

CONSERVATION

- Keep at a temperature between 2 ° C and 30 ° C, away from light.
- Once opened for the first time, the duration of the product is 3 months.

CONDITION OF SALE

Sale with Veterinary Medical prescription.

Peru: Free Sale

PRESENTATION

20 mL bottle

PREPARED BY

Laboratorio Drag Pharma Chile Invetec S.A.

RECORDS

Chile: Reg. SAG Nº 2210-B

Perú: Reg. SENASA F.83.47.I.0090

COUNTRIES WHERE IT IS MARKETED

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