

FARBIO-OTIC

**MOMETASONE - GENTAMICIN -
CLOTRIMAZOLE**

PHARMACEUTICAL FORM:
OTIC EMULSION

COMPOSITION:


Each 100 g contains:

Mometasone furoate	0.100 g
Gentamicin sulfate	0.500 g
Clotrimazole	1.400 g
Excipients q.s.	100 g

SPECIES:

•Canine

DOSAGE:

DOSAGE AND ADMINISTRATION		
SPECIE	WEIGHT	PRACTICAL DOSAGE
 CANINE	Up to 15 kg	4 drops in each ear
	15 kg and over	8 drops in each ear
<p>Route of administration: Topical Apply the product every 24 hours for 7 days or as directed by the attending veterinarian.</p>		

INDICATIONS AND USE:

FARBIO-OTIC is an otic emulsion with anti-inflammatory, antibacterial, and antifungal activity. It is indicated for use in dogs for the treatment of otitis media and externa caused by pathogens susceptible to gentamicin and clotrimazole.

ROUTE OF ADMINISTRATION:

•Topical (otic)

PHARMACOKINETICS:

Mometasone Furoate:

Rapid hepatic clearance and high plasma protein binding (free fraction <1%) contribute to the low systemic bioavailability of mometasone furoate (MF) and to the absence of suppression of the HPA axis at the recommended doses.

Gentamicin:

The polycationic nature of aminoglycosides makes them highly water-soluble and poorly lipid-soluble; therefore, they cross biological membranes very slowly. Gentamicin is well and rapidly absorbed when administered via the subcutaneous route and has a bioavailability greater than 90%. Plasma protein binding is very low (10–20%), and it does not penetrate the CNS or the vitreous humor, although it can cross the placental barrier. It also does not cross cellular membranes, making it ineffective against microorganisms that reproduce intracellularly. Approximately 85% of this drug is eliminated by glomerular filtration.

Clotrimazole:

Clotrimazole is not absorbed or is only minimally absorbed (3%) when applied topically to mucous membranes, and approximately 0.5% is absorbed through intact skin. Any absorbed amount is metabolized and excreted via the bile, with low levels of active drug and a predominance of metabolites in the urine.

MECHANISM OF ACTION:

Mometasone furoate confers topical anti-inflammatory properties by blocking the release of arachidonic acid and its subsequent conversion into eicosanoids. It also inhibits the synthesis of various inflammatory cytokines (e.g., IL-1, TNF-alpha) by inhibiting the pro-inflammatory transcription factor NF-κB. In addition, it reduces DNA synthesis through an antimitotic effect on epidermal cells. It also inhibits the migration of leukocytes and macrophages to the affected area, thereby reducing erythema, pruritus, and edema.

Gentamicin is actively transported across the bacterial cell membrane and inhibits protein synthesis by irreversibly binding to the 30S ribosomal subunit.

Clotrimazole acts by inhibiting ergosterol synthesis in the fungal cell membrane. Its potency is related to its ability to bind to cytochrome P-450, which is required for ergosterol synthesis.

PRECAUTION, WARNINGS AND CONTRAINDICATIONS:

- Avoid contact with eyes, skin, and mucous membranes; wear gloves.
- Wash hands after each application.
- The attending veterinarian should adjust the duration of treatment according to the severity of clinical signs, always taking into account the potential side effects associated with frequent and prolonged use.
- Do not administer to pregnant females.
- Do not administer if ulcerated or burned skin is observed.
- Do not administer if tympanic membrane rupture is suspected or present.
- Do not administer in patients with known hypersensitivity to any of the components.
- Do not allow the patient to lick or chew the treated areas for at least 20 to 30 minutes after application.

DRUG INTERACTIONS:

Not reported.

SIDE EFFECTS:

As a topical-use product and at the recommended concentrations, its active ingredients are relatively safe when administered via this route and at these concentrations. No potential side effects were observed, and the likelihood of adverse effects is almost negligible.

WITHDRAWAL: None .

ANTIDOTE: None.

STORAGE: Store in a cool, dry place, protected from light, at a temperature between 15°C and 30°C. **Keep out of reach of children and domestic animals.**

SALE: Veterinary prescription only.

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