



Tobramycin

Mycinidin®

3 mg/mL (0.3% w/v)
Sterile Ophthalmic Solution
(Eye Drops)

ANTIBACTERIAL (AMINOGLYCOSIDE)
FOR EXTERNAL USE ONLY

FORMULATION:

Each mL contains:
Tobramycin 3 mg

PRODUCT DESCRIPTION:

Clear, colorless to slightly yellowish solution.

PHARMACEUTICAL FORM:

Sterile Ophthalmic Solution (Eye Drops).

THERAPEUTIC INDICATIONS:

Tobramycin (Mycinidin®) 0.3% Sterile Ophthalmic Solution is a topical antibiotic indicated in the treatment of superficial ocular infections caused by susceptible bacteria.

- Conjunctivitis
- Keratitis
- Keratoconjunctivitis
- Corneal ulcers
- Blepharitis
- Blepharoconjunctivitis
- Acute meibomianitis

DOSAGE AND ADMINISTRATION:

Mild-Moderate infections:
Instill 1 to 2 drops into the affected eye(s) every 4 - 6 hours.

Severe infections:
Instill 2 drops into the eye(s) hourly until improvement. Reduce treatment prior to discontinuation.

CONTRAINDICATIONS:

Tobramycin (Mycinidin®) 0.3% Sterile Ophthalmic Solution is contraindicated in patients with known hypersensitivity to any of its components.

SPECIAL WARNINGS AND PRECAUTIONS FOR USE:

- Tobramycin (Mycinidin®) Ophthalmic Solution is not for injection into the eye.
- Prolonged therapy with Tobramycin (Mycinidin®) as with antibiotics may result in super-infection with non-susceptible organisms including fungi.
- Cross-sensitivity to other aminoglycoside antibiotics may occur.
- Patients should discontinue the drug at the first sign of skin rash or other allergic reactions.
- Contact lenses should be removed prior to administration of Tobramycin (Mycinidin®). Lenses may be re-inserted 15 minute



following administration of the drug.

- Patient should avoid allowing the tip of the dispensing container to contact the eye(s) or surrounding structures to avoid bacterial contamination.
- If more than one topical ophthalmic drug is being used, the drugs should be administered at least 10 minutes apart.

INTERACTION WITH OTHER MEDICINAL PRODUCTS AND OTHER FORMS OF INTERACTION:

No specific interaction studies were performed with Tobramycin (Mycinidin®) 0.3% Sterile Ophthalmic Solution.

Pregnancy and Lactation

Tobramycin (Mycinidin®) 0.3% Sterile Ophthalmic Solution should be used with caution in pregnancy and lactation. The drug may be used only if the potential benefit justifies the potential risk.

Effects on ability to drive and use machines

Not reported.

ADVERSE DRUG REACTIONS:

Sensitivity reactions such as transient irritation, burning, itching, swelling, stinging, and conjunctival erythema may occur in some patients.

OVERDOSE AND TREATMENT:

Signs and symptoms of an overdose may be similar to adverse reaction effects seen in some patients.

PHARMACOLOGICAL PROPERTIES:

Pharmacodynamic properties

Therapeutic group: ophthalmologicals, anti-infectives

Mode of action

Tobramycin (Mycinidin®) 0.3% Sterile Ophthalmic Solution is a potent, broad-spectrum, fast-working bactericidal aminoglycoside antibiotic. It exerts its primary effect on bacterial cells by inhibiting polypeptide assembly and synthesis on the ribosome.

Spectrum of antibacterial activity

Tobramycin (Mycinidin®) 0.3% Sterile Ophthalmic Solution is active against wide range of G-ve and G+ve bacteria including *Pseudomonas aeruginosa*, *Haemophilus influenzae* and *aegypticus*, *Neisseria sp.*, *Klebsiella pneumoniae*, *E.coli*, *Proteus sp.*, *Enterobacter aerogenes*, *Moraxella lacunata*, *Acinetobacter calcoaceticus*, *Staphylococci sp.* including *S. aureus*, *Streptococci sp.* including *Strep. pneumoniae* and *beta-haemolytic streptococci*.

Other information

Cross-resistance between aminoglycosides (e.g. gentamycin and tobramycin) is due to the specificity of the enzyme modifications, Adenyltransferase (ANT) and Acetyltransferase (ACT). However, cross-resistance varies between the aminoglycoside antibiotic due to the differing specificity of the various modifying enzymes. The most common mechanism of acquired resistance to aminoglycosides is antibiotic inactivation by plasmid and transposon-encoded modifying enzymes.

Pharmacokinetic properties

Following topical ocular administration, only a small amount of Tobramycin crosses the undamaged corneal barrier.

SHELF LIFE:

Opened: discard one month after first opening.

CAUTION:

Foods, Drugs, Devices, and Cosmetics Act prohibits dispensing without prescription.

“For suspected adverse drug reaction, report to the FDA: www.fda.gov.ph.

Seek medical attention immediately at the first sign of any adverse drug reaction.”

STORAGE CONDITION:

Store at temperatures not exceeding 30°C.

Keep out of reach of children.

AVAILABILITY:

LDPE white opaque plastic droptainer in 5 mL (net content). Box of 1's

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Manufactured by:
EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES CO. (EIPICO)

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