Tobrastill 0.3% EYE - DROPS SOLUTION
Tobramycin

Composition.
100 ml of solution contain: Active ingredient: tobramycin 0.3 g.
Excipients: tyloxapol, boric acid, anhydrous sodium sulphate, sodium chloride, benzalkonium chloride, purified water.

Pharmaceutical form and content.
5 ml eye-drops solution with dropper.

Pharmacotherapeutic category.
Antibiotic.

Holder of registration and manufacturer.
BRUSCHETTINI s.r.l. - Genova (Italy).

Manufacturer and controller of the finished product.
BRUSCHETTINI s.r.l. - Genova (Italy).

Therapeutic indications.
The product is recommended in the treatment of eye and ocular adnexa infections caused by bacteria sensitive to Tobramycin: acute catarrhal conjunctivitis; sub-acute and chronical conjunctivitis; blepharitis; bacterial keratitis; dacryocystitis; pre and post-operative prophylaxis in operation of the anterior segment.

Contraindications.
Hypersensitivity to one of the product components and to any chemically related substances.

Precautions for use.
Like other antibiotics, the prolonged use can cause the growth of resistant microrganisms, including fungi. In case amino-glycoside antibiotics are administered by systemic route together with the topical administration of Tobramycin, the total serum concentration must be carefully controlled.

Interactions.
Tyloxapol is incompatible with tetracycline.

SPECIAL WARNINGS

Pregnancy and lactation.
In pregnancy and first childhood the product shall be administered only in case of real need, under direct doctor's control. The product

must not be used during lactation. The lactation must be suspended in case the doctor judges the treatment indispensable.

Dosage, method and frequency of administration.

Instill 2 drops into the conjunctive bag four times a day in acute cases, and three times a day for the chronic forms, according the physician advice. Do not exceed the dosage or the treatment period suggested by the physician.

Overdose.

Overdose cases are not known.

Undesirable effects.

As all the amino-glycoside antibiotics for ocular topic use, the product could cause allergic reactions or local hypersensitivity such as itching, eyelid swelling or conjunctival erythema.

These phenomena were recorded in at least 3% of the treated patients.

To follow these insert advices reduces the risk of undesirable effects.

It is advisable that the patient informs the physician or the chemist about whatever side effect not described in this insert.

Expiry and storage.

Check the expiry date printed on packaging

Expiry date refers to product correctly packed and stored.

Warnings.

As TOBRASTILL eye-drops, solution contains the preservative benzalkonium chloride, this may cause eye irritation and is known to discolour soft contact lenses. Therefore, patient must remove contact lenses prior to application of TOBRASTILL and be instructed to wait 15 minutes after instillation of TOBRASTILL before inserting contact lenses.

Do not use the medicament after the expiry date printed on its packaging.

Store the product at a temperature not higher than 25°C.

The product must be used within 30 days after first opening.

Keep out of the reach and sight of children.

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BRUSCHETTINI s.r.l.
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