Intobac™

Tobramycin

Presentation

Intobac™ nebuliser solution: Each ampoule contains 5 ml solution for inhalation of Tobramycin USP 300 mg.

Description

Tobramycin nebuliser solution is a sterile, clear, slightly yellow, non-pyrogenic, aqueous sloution with the pH and salinity adjusted specifically for the administration by a nebuliser. Tobramycin is an aminoglycoside antibiotic and acts primarily by disrupting protein synthesis, leading to alter cell membrane permeability & eventual cell death. It is bactericidal & active against wide range of gram negative organisms including *Pseudomonas aeruginosa.*

Indications

Tobramycin nebuliser solution is indicated for the management of cystic fibrosis in patients with *Pseudomonas aeruginosa*.

Safety & efficacy have not been demonstrated in patients below the age of 6 years, patients with a forced expiratory volume <25% or >75% predicted, or patients colonized with *Burkholderia cepacia*.

Dosage and Administration

The 300 mg dose of Tobramycin is same for all patients regardless of age or weight (Tobramycin has not been studied in patients less than 6 years old). The recommended dose is one single-use ampoule (300 mg) to be inhaled b.i.d for 28 days. The dose should be taken as close to 12 hours apart as possible; they should not be taken less than 6 hours apart.

If patient is taking several medications, the recommended order is as follows: bronchodilator first, followed by chest physiotherapy, then other inhaled medications & finally Tobramycin.

Patient should take Tobramycin in repeated cycles of 28 days on drug, followed by 28 days off drug.

Adverse Effects

Inhaled Tobramycin is generally well tolerated; voice alterations and tinnitus are more common in the on-drug periods. However, all the episodes are transient and resolved without discontinuation of the regimen. Other side effects, like, dizziness and increase in serum creatinine, etc are similar to those occurring with placebo.

Contraindications

Tobramycin is contraindicated in patients with a known hypersensitivity to any aminoglycoside. Tobramycin nebuliser solution must only be used by inhalation from a nebuliser and must not be injected or swallowed.

Precautions

It should be used with care in patients with known or suspected renal, auditory, vestibular or neuromuscular dysfunction. Patients receiving concomitant aminoglycoside therapy should be monitored as clinically appropriate. Following complications may occur with Tobramycin: ototoxicity, muscular disorders, bronchospasm and nephrotoxicity.

Drug Interactions

Patients taking Tobramycin concomitantly with beta-agonists, inhaled corticosteroids, other anti-pseudomonas antibiotics or parenteral aminoglycosides demonstrated adverse experience profiles. Concurrent and/or sequential use of Tobramycin with other drug and with neurotoxic or ototoxic potential should be avoided. Some diuretics can enhance its toxicity. Tobramycin should not be administered concomitantly with ethacrycnic acid, furosemide, urea or mannitol.

Pregnancy & Lactation

Teratogenic effect- Pregnancy category D. It is not recommended during pregnancy & lactation.

Storage

Store under refrigeration at 2-8 ^{0}C and protected from light. Slight color change when unrefrigerated does not indicate any change in the quality of the product. The preparation must not be used if it is cloudy or particles appear in the solution or has been stored at room temperature for over 28 days.

Commercial Pack

Intobac™ nebuliser solution: Each box contains 5 ampoules in a blister pack.

Manufactured by
Incepta Pharmaceuticals Ltd
Savar, Dhaka, Bangladesh

V.N. 01
ITB