

# Tobasol®

Tobramycin USP 300 mg/5 ml

Sterile Respirator Solution

Solution for inhalation (not for injection)

## Description

Tobasol® Respirator Solution is an aqueous solution of Tobramycin. Tobramycin is an aminoglycoside antibiotic and acts primarily by disrupting protein synthesis, leading to altered cell membrane permeability, and eventual cell death. Tobramycin is bactericidal and is active against wide range of Gram-negative organisms including *Pseudomonas aeruginosa*.

## Indications

Tobasol® Respirator Solution is indicated for the management of cystic fibrosis patients with *Pseudomonas aeruginosa*.

Also indicated for severe COPD patients colonized with *Pseudomonas aeruginosa*.

Safety and 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 recommended dosage for, both adult and paediatric patients, 6 years of age and older, is one single-use ampoule (300 mg) administered b.i.d for 28 days. Dosage is not adjusted by weight. The doses should be taken as close to 12 hours apart as possible; they should not be taken less than 6 hours apart.

If you are taking several medications, the recommended order is as follows: bronchodilator first, followed by chest physiotherapy, then other inhaled medications and finally Tobasol®.

You should take Tobasol® in repeated cycles of 28 days on drug, followed by 28 days off drug. You should take Tobasol® twice a day during the 28 day period on drug.

## Side 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. Others like dizziness and increase in serum creatinine were similar to those occurring with placebo.

## Contraindications

Tobasol® is contraindicated in patients with a known hypersensitivity to any aminoglycoside.

## Warnings

Tobasol® Respirator Solution must only be used by inhalation from a nebulizer 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. It must be used with caution in patients with ototoxicity and nephrotoxicity. Discuss the use of Tobramycin with your doctor if you have kidney problems or changes in hearing. If you are a nursing mother, pregnant or want to become pregnant, ask your doctor about the possibility of Tobramycin causing any harm.

## Drug Interactions

Patients taking Tobasol® concomitantly with beta-agonists, inhaled corticosteroids, other anti-pseudomonal antibiotics or parenteral aminoglycosides demonstrated adverse experience profiles.

**Pharmaceutical Precaution**

Store under refrigeration at 2o C-8o C, and protected from light. Slight color change when unrefrigerated do not indicate any change in the quality of the product. The preparation must not be used if it is cloudy, particles appear in the solution or has been stored at room temperature for over 28 dyas. For use only under the prescription of a registered physician.

Do not use Tobasol® beyond the expiration date stamped on the ampoule.

**Commercial Pack**

Tobasol® respirator solution: Box containing 1 x 5 ampoules of 5 ml. Each 5 ml ampoule contains Tobramycin USP 300 mg.

Manufactured by

beximco pharmaceuticals ltd.

TONGI, bangladesh IL 6776 201011

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