TOBI® Podhaler®

Tobramycin Inhalation Powder 28 mg per capsule

How To Prescribe

INDICATION

TOBI® PODHALER® (Tobramycin Inhalation Powder) 28 mg per capsule is indicated for the management of cystic fibrosis patients with *Pseudomonas aeruginosa*.

Safety and efficacy have not been demonstrated in patients under the age of 6 years, patients with forced expiratory volume in 1 second (FEV_1) <25% or >80% predicted, or patients colonized with *Burkholderia cepacia*.

IMPORTANT SAFETY INFORMATION

TOBI PODHALER is contraindicated in patients with known hypersensitivity to any aminoglycoside.

Bronchospasm can occur with inhalation of TOBI PODHALER. Bronchospasm should be treated as medically appropriate.

Caution should be exercised when prescribing TOBI PODHALER to patients with known or suspected auditory, vestibular, renal, or neuromuscular dysfunction.

See inside for Continued Important Safety Information.

Click here for full Prescribing Information.

VIATRIS™

TOBI® PODHALER® Prescription Checklist

The following is intended to provide general information for prescribing TOBI PODHALER for medically appropriate patients. Each CF center remains responsible for properly submitting all information for their patients.*

When prescribing TOBI PODHALER for a patient for the first time, be sure to note the following information:

- ☑ Documented FEV_1 of the patient
- ☑ Positive culture for *Pseudomonas Aeruginosa (Pa)*
- ☑ Age of patient is 6 or above
- ☑ ICD 10 code for Cystic Fibrosis diagnosis - E.84
- ☑ Confirm cycle of 28 days on/28 days off (number of capsules – 224)
- ☑ Number of prescribed refills or quantity limits

For Prior Authorizations that may request more patient information, please be sure to have the following information ready to share:

Patient History of *Pseudomonas Aeruginosa* infections

Documentation of previous inhaled antibiotic use (if applicable)

-Nebulized tobramycin solution, KITABIS®, BETHKIS®

Clinical rationale for why the patient cannot continue with current therapy. (What is the impact to the patient if they do not have access to TOBI PODHALER.)

- Side effects
- Exacerbation history
- Tolerability
- Hospitalizations
- Adherence

*Viatris does not guarantee coverage or payment for TOBI PODHALER

This information does not establish clinical comparability of products and should not be seen as making a claim regarding safety or efficacy. The approved uses of the products discussed in this brochure may vary. Please refer to the product prescribing information for more information.

IMPORTANT SAFETY INFORMATION (Continued)

Ototoxicity, as measured by complaints of hearing loss or tinnitus, was reported by patients in the TOBI PODHALER clinical studies. Tinnitus may be a sentinel symptom of ototoxicity, and therefore the onset of this symptom warrants caution. Ototoxicity, manifested as both auditory and vestibular toxicity, has been reported with parenteral aminoglycosides. Vestibular toxicity may be manifested by vertigo, ataxia, or dizziness.

TOBI PODHALER Savings Card

Visit ActivateTheCard.com/TOBI to see eligibility requirements and to view full terms and conditions†

Not an actual card.

Customizable patient support program

podcare+®

Patients may choose from a variety of support services based on their individual needs

Benefits Investigation

Find out if TOBI PODHALER is covered by your patient's health insurance

Prior Authorization (PA) Support

Assist with PA requests and help to facilitate patient access to medication

Electronic PA Support

Seamless integration with CoverMyMeds® to efficiently coordinate PA process

Individual Therapy Support

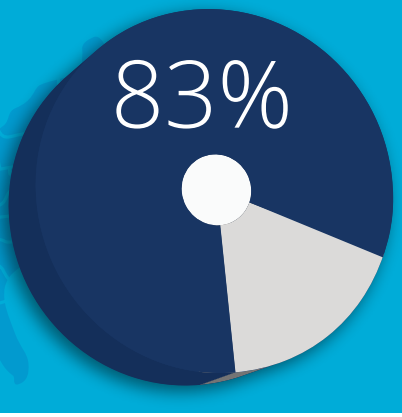
Provides regular check in calls to assist patients with PODCARE+® services

Visit TOBIPODHALERHCP.com or call 1-877-999-TOBI (8624) to enroll your eligible patients‡

†This Savings Card may be used to reduce the amount of any eligible patient's out-of-pocket costs for TOBI® PODHALER® (Tobramycin Inhalation Powder) up to a maximum of $14,000 per calendar year while this program remains in effect, with no monthly limit. Eligibility restrictions apply. This offer is not valid for patients enrolled in federal or state healthcare programs, such as Medicare (Part D or otherwise), Medicaid, Medigap, VA, DoD or TRICARE, and not valid for uninsured patients (except for commercially insured patients without coverage for TOBI® PODHALER®). This offer is void where prohibited or restricted by law. Mylan Specialty L.P., a Viatris Company, reserves the right to amend or end this program at any time without notice. For full terms and conditions, visit www.activatethecard.com/tobi.

‡The PODCARE+ Patient Support Program Hotline is available Monday through Friday, 8 am to 8 pm ET.

TOBI PODHALER is COVERED by over 83% of Commercial and Medicaid Insurance plans combined nationwide*



*Covered designation is determined by the plan. Covered does not mean there are no formulary restrictions or utilization management. Formulary designations (e.g., preferred, non-preferred, specialty) are based on individual plan definitions and are not determined by FINGERTIP FORMULARY® or Viatris. Formulary data is provided by FINGERTIP FORMULARY and is current as of June 29, 2022. Formularies or patient out-of-pocket costs vary and are subject to change without notice; please check directly with the plan to determine the most up-to-date information. Not a guarantee of coverage or payment (full or partial); state of residency may impact coverage. Restrictions such as quantity limits, prior authorizations, or step edits, may also vary by tier and plan. Individual costs and coverage may vary. Please check with the health plan directly to determine coverage for an individual product.

IMPORTANT SAFETY INFORMATION (Continued)

Caution should be exercised when prescribing TOBI PODHALER to patients with known or suspected renal dysfunction. Nephrotoxicity was not observed during TOBI PODHALER clinical studies but has been associated with aminoglycosides as a class.

TOBI PODHALER should be used cautiously in patients with neuromuscular disorders, such as myasthenia gravis or Parkinson's disease, since aminoglycosides may aggravate muscle weakness because of a potential curare-like effect on neuromuscular function.

Aminoglycosides can cause fetal harm when administered to a pregnant woman. Patients who use TOBI PODHALER during pregnancy, or who become pregnant while taking TOBI PODHALER, should be apprised of the potential hazard to the fetus. The amount of tobramycin excreted in human breast milk is unknown. However, systemic absorption of tobramycin following inhaled administration is expected to be minimal. A decision should be made whether to discontinue nursing or TOBI PODHALER. TOBI may cause intestinal flora alteration. Advise a woman to monitor the breastfed infant for loose or bloody stools and candidiasis.

Patients receiving concomitant TOBI and parenteral aminoglycoside therapy should be monitored as clinically appropriate for toxicities associated with aminoglycosides as a class. Serum tobramycin levels should be monitored.

Concurrent and/or sequential use of TOBI PODHALER with other drugs with neurotoxic, nephrotoxic, or ototoxic potential should be avoided. Some diuretics can enhance aminoglycoside toxicity by altering antibiotic concentrations in serum and tissue. TOBI PODHALER should not be administered concomitantly with ethacrynic acid, furosemide, urea, or mannitol.

In a clinical trial, the most commonly observed adverse events with TOBI PODHALER occurring at a frequency of at least 10%, were cough, lung disorder, productive cough, dyspnea, pyrexia, oropharyngeal pain, dysphonia, hemoptysis, and headache.

Click here for full Prescribing Information.

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