Not actual size

TOBI® Podhaler®

Tobramycin Inhalation Powder 28 mg per capsule

Prescribing TOBI PODHALER

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.

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.

See inside for continued Important Safety Information and see accompanying full Prescribing Information.

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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 of 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 years 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

Note: A prior authorization to indication for the class may still be required.

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*

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
- Tolerability
- Adherence
- Exacerbation history
- Hospitalizations

*Viatris does not guarantee coverage or payment for TOBI PODHALER. Check with your patient's insurance provider for coverage rules and restrictions.

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.

CF: Cystic fibrosis; FEV_1: Forced expiratory volume in one second; ICD: International Classification of Diseases

IMPORTANT SAFETY INFORMATION (Continued)

Cases of ototoxicity with aminoglycosides have been observed in patients with certain variants in the mitochondrially encoded 12S rRNA gene (*MT-RNR1*), particularly the m.1555A>G variant. Ototoxicity occurred in some patients even when their aminoglycoside serum levels were within the recommended range. Mitochondrial DNA variants are present in less than 1% of the general US population, and the proportion of the variant carriers who may develop ototoxicity as well as the severity of ototoxicity is unknown.

See front and back cover for Indications, continued Important Safety Information, and see accompanying full Prescribing Information.

podcare+®

PODCARE+ offers support for your patients that have been prescribed TOBI PODHALER

covermymeds®

Electronic PA Support

Seamless integration with CoverMyMeds® to efficiently coordinate PA process

TOBI PODHALER Savings Card

Eligible, commercially-insured patients may pay as little as $0 for a TOBI PODHALER prescription†

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

Not an actual card

Visit TOBIPODHALERHCP.com or call 1-877-999-TOBI (8624) for more information‡

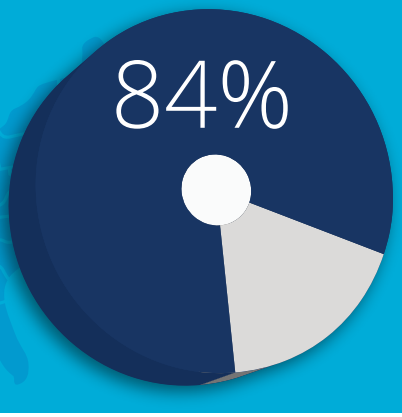
†This Savings Card may be used to reduce the amount of an eligible patient's out-of-pocket costs for TOBI PODHALER up to the full amount of the patient's out-of-pocket cost per 28 day prescription, up to an aggregate maximum of $14,000 per calendar year, while this program remains in effect. No other purchase is necessary. Valid prescription with Prescriber ID# is required. 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.

Eligibility Requirements: This Savings Card can be redeemed only by patients or patient guardians who are 18 years of age or older and who are residents of the United States and its territories. Patients must have commercial insurance. This program is not valid for uninsured patients (but may be used by commercially insured patients without coverage for TOBI PODHALER and patients who are covered by any state or federally funded healthcare program, including but not limited to any state pharmaceutical assistance program, Medicare (Part D or otherwise), Medicaid, Medigap, VA or DOD, or TRICARE (regardless of whether TOBI PODHALER is covered by such government program); not valid if the patient is Medicare eligible and enrolled in an employer-sponsored health plan or prescription benefit program for retirees; and not valid if the patient's insurance plan is paying the entire cost of this prescription. This program is void outside the US and its territories or where prohibited by law, taxed, or restricted. Absent a change in Massachusetts law, this program will no longer be valid for Massachusetts residents as of January 1, 2026.

This Savings Card is not health insurance. This Savings Card is not transferable, and the amount of the savings cannot exceed the patient's out-of-pocket costs. This program cannot be combined with any other rebate/coupon, cash discount card, free trial, or similar offer for the specified prescription. This Savings Card is not redeemable for cash.

‡The PODCARE+ Hotline is available to answer your questions, Monday through Friday, 8am to 5pm ET.

TOBI PODHALER is COVERED by over 84% of Commercial and Medicaid Insurance plans combined nationwide¶§



¶Preferred designation is determined by the plan, i.e. Express Scripts/OptumRx. Preferred does not mean there are no formulary restrictions or utilization management. Commercial plan coverage for 2023 based on 179,707,720 members. Formulary data is provided by Fingertip Formulary® and is current as of May 30, 2023. Formularies 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. Formulary designations (e.g., preferred, non-preferred, specialty) are based on individual plan definitions and are not determined by Fingertip Formulary or Viatris Specialty. Individual costs and coverage may vary. Please check with the health plan directly to determine coverage for an individual product.

§Data on file - May 30, 2023.

IMPORTANT SAFETY INFORMATION (Continued)

In case of known maternal history of ototoxicity due to aminoglycoside use or a known mitochondrial DNA variant in the patient, consider alternative treatments other than aminoglycosides unless the increased risk of permanent hearing loss is outweighed by the severity of infection and lack of safe and effective alternative therapies.

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.

Please see front cover and inside for Indications, continued Important Safety Information, and see accompanying full Prescribing Information.

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