Take back time with TOBI® PODHALER®

(Tobramycin Inhalation Powder) 28 mg per capsule

Not actual size.

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.

TOBI® Podhaler®
Tobramycin Inhalation Powder
28 mg per capsule

Please see additional Important Safety Information on page 22.
Click here for Full Prescribing Information.

VIATRIS™

The only inhaled antipseudomonal treatment using dry powder formulation

Twice-daily treatment with fast administration time of **2 to 7 minutes** as observed in a clinical trial[1*]

No nebulizer, refrigeration or power source needed

No washing, drying, or disinfection required

Simply wipe clean with a dry cloth[1]

TOBI PODHALER is **compact and lightweight**

Each day, **patients can easily carry** what they need while on treatment

* Randomized, open-label, active-controlled study to evaluate safety.

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.

Please see additional Important Safety Information on page 22.
Click here for Full Prescribing Information.

PULMOSPHERE® Technology

TOBI PODHALER delivers proprietary PULMOSPHERE powder particles[2]

- Low in density
- Light and porous - Hollow particle
- Particle size: median geometric diameter is 1.7-2.7 µm
- Minimal effort is required to disperse the particles
- Low particle-to-particle cohesion supporting dispersibility
- Lung deposition to both central and peripheral airways

Watch a video on PULMOSPHERE Technology by visiting **TOBIPODHALERHCP.com or scanning the QR code**

IMPORTANT SAFETY INFORMATION (Continued)

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.

Please see additional Important Safety Information on page 22.
Click here for Full Prescribing Information.

In a clinical study, patients with moderate to severe CF were able to use the PODHALER device[1]

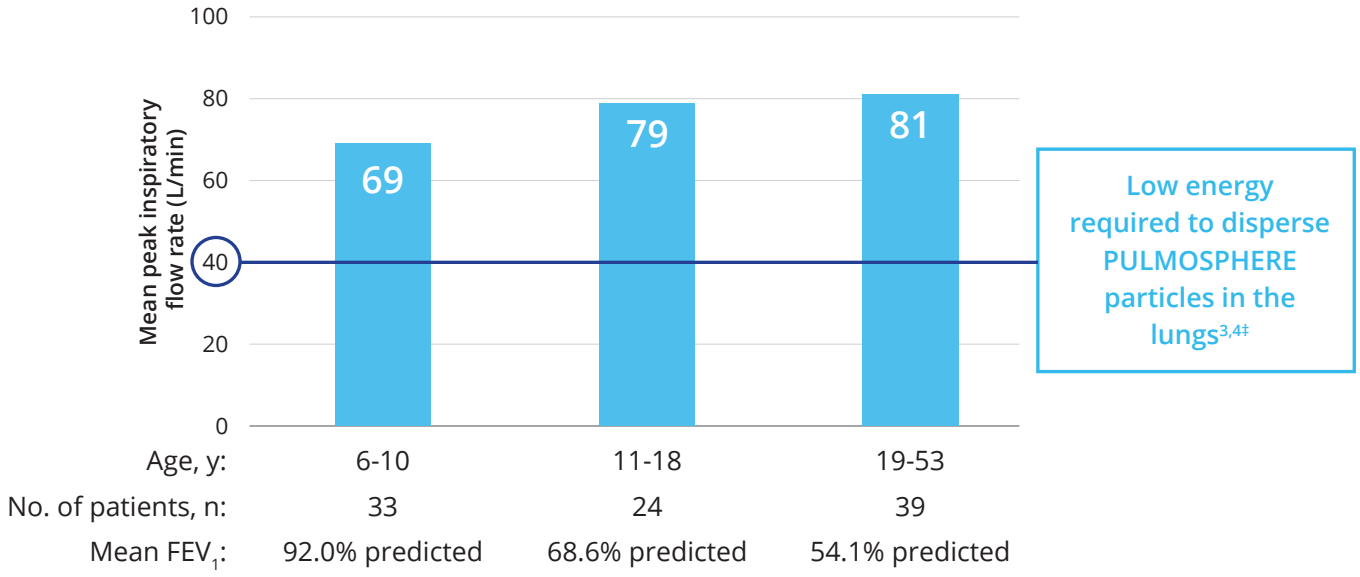
Patient types that were able to generate the inspiratory flow rates and volumes required to receive medication included:[1]

Older patients with significant disease progression and associated decreases in FEV_1

Younger patients (aged >6 years) with inhaled volumes <1 L

Patients followed the Instructions for Use. Pediatric patients aged 6 to 10 years of age with FEV_1 <40% predicted were not evaluated

Mean inspiratory flow rate of 96 CF patients exceeded the minimal requirement for dispersion of PULMOSPHERE particles[3,4‡§]



CF patient profiles with various degrees of lung function[3,4‡]

‡This study explored inspiratory variables of 96 patients with CF aged ≥6 years with varying degrees of lung disease while inhaling through mouthpieces with resistance that simulated dry-powder inhaler devices. Enrolled patients were aged 6 to 53 years, with FEV_1 19% to 126% predicted.[3,4] TOBI PODHALER is indicated for patients with an FEV_1 25% to 80% predicted.[1]

§A flow rate of 40 L/min represents a flow rate more than 2 standard deviations below the mean peak inspiratory flow rates measured for pediatric patients in the study.[2]

Please see additional Important Safety Information on page 22.

Click here for Full Prescribing Information.

Dosing

- One treatment cycle consists of **28 days on and 28 days off** treatment[1]
- Each dose of 4 capsules should be taken as close to 12 hours apart as possible. Each dose should not be taken less than 6 hours apart[1]
- The powder from all 4 capsules must be inhaled to receive the full dose of 112 mg. **Inhale 2 times from each capsule in order to empty it**[1]
- Capsules are for use with the PODHALER device only[1]
- TOBI PODHALER capsules must not be swallowed and are for oral inhalation only[1]
- Capsules should always be stored in the blister card, each capsule should **only be removed IMMEDIATELY BEFORE USE**[1]

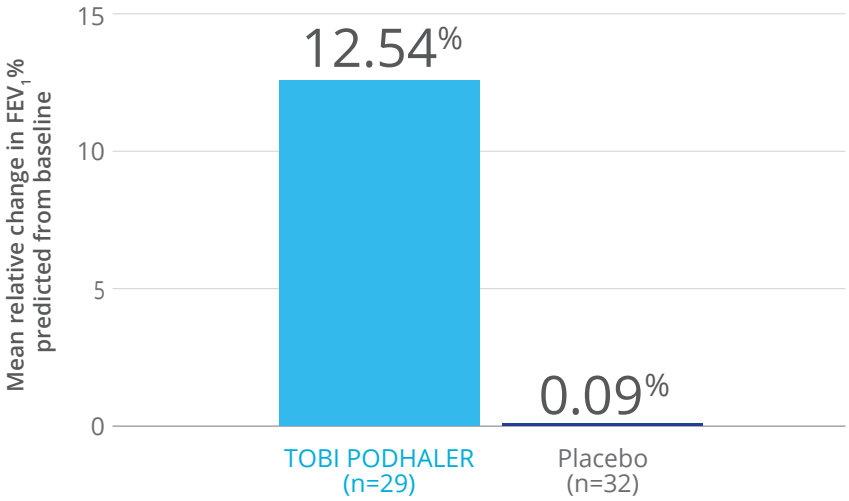
IMPORTANT SAFETY INFORMATION (Continued)

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.

Please see additional Important Safety Information on page 22.
Click here for Full Prescribing Information.

In a placebo-controlled study, TOBI PODHALER significantly improved lung function

Mean relative change in FEV_1% predicted from baseline to the end of first 28 days on treatment (*P*=0.002)[1†]



Primary endpoint in EVOLVE (Study 2)

Mean absolute changes in FEV_1% predicted

TOBI PODHALER: +6.38%; placebo: -0.52%; difference of 6.90% (95% CI: 2.40, 11.40)[1]

EVOLVE: EValuate tObramycin inhaLed dry powder efficacy Versus placebo in cystic fibrosis patiEnts.

[†]Each cycle consisted of 28 days on treatment followed by 28 days off treatment.[1]

EVOLVE was a 24-week, randomized, double-blind (during Cycle 1) trial in patients aged 6 to 21 years with CF, *Pa*, and FEV_1 ≥25% and ≤80% predicted at screening. The first cycle was double-blind and placebo-controlled with eligible patients randomized 1:1 to TOBI PODHALER (four 28-mg capsules twice daily) or placebo. For Cycles 2 and 3, patients who were initially randomized to placebo received TOBI PODHALER. Of the 79 patients included in the prespecified interim analysis, 18 were excluded due to a failure to meet spirometry quality review criteria, which resulted in a total of 61 patients included in the primary analysis.[1,5]

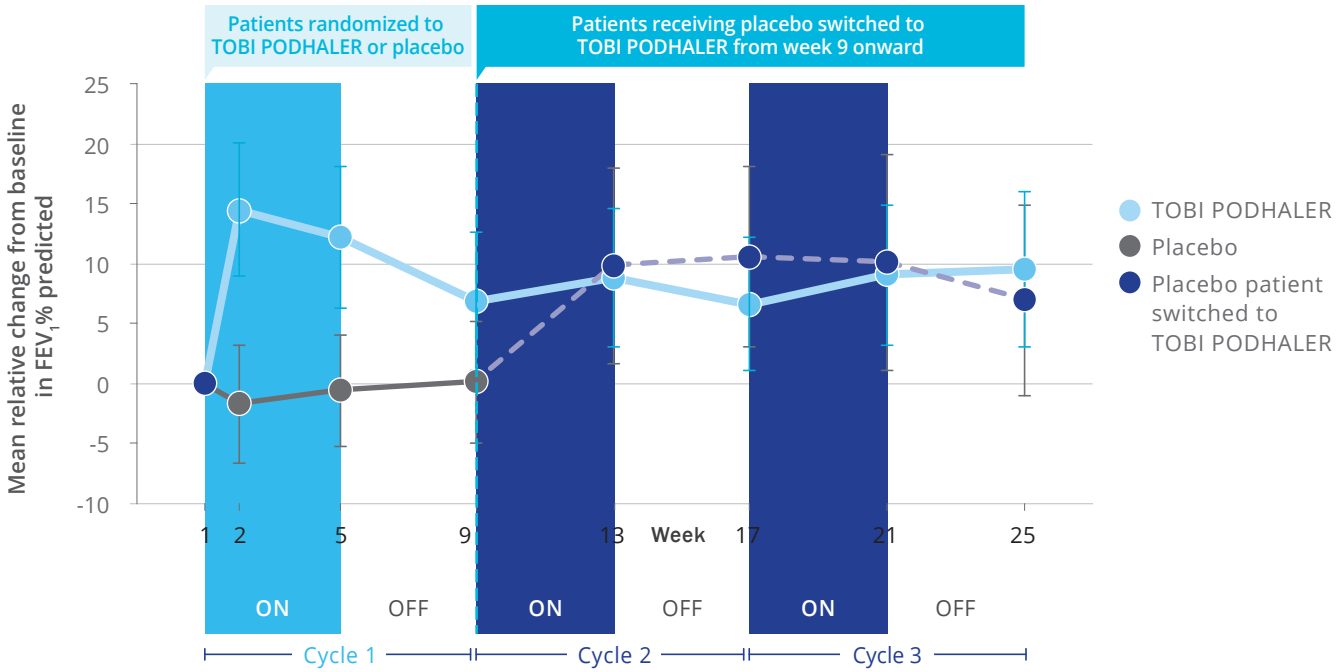
IMPORTANT SAFETY INFORMATION (Continued)

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.

Please see additional Important Safety Information on page 22.
Click here for Full Prescribing Information.

After cycle 1, patients who switched from placebo to TOBI PODHALER showed improvement in their lung function

Mean relative change in FEV_1% predicted from baseline (Cycles 1 to 3)[1]



Error bars represent mean relative change (95% CI)[1]

Improvements in lung function were achieved during the subsequent cycles of treatment with TOBI PODHALER, although the magnitude of improvement was reduced.[1]

IMPORTANT SAFETY INFORMATION (Continued)

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 additional Important Safety Information on page 22.
Click here for Full Prescribing Information.

TOBI® Podhaler®
Tobramycin Inhalation Powder 28 mg per capsule

In a placebo-controlled study,

Fewer respiratory-related hospitalizations and IV antipseudomonal antibiotics

64%

Reduction in the percentage of patients with respiratory-related hospitalizations in clinical study comparing TOBI PODHALER and placebo[1,5]

Secondary endpoint in EVOLVE (Study 2, Cycle 1)[1]

- 4.4% in the TOBI PODHALER treatment group vs 12.2% in the placebo group

15%

Reduction in the percentage of patients needing IV antipseudomonal antibiotics in clinical study comparing TOBI PODHALER and placebo[1,5]

Secondary endpoint in EVOLVE (Study 2, Cycle 1)[1]

- 8.7% in the TOBI PODHALER treatment group vs 10.2% in the placebo group

EVOLVE was a 24-week, randomized, double-blind (during Cycle 1) trial in patients aged 6 to 21 years with CF, *Pa*, and FEV_1 ≥25% and ≤80% predicted at screening. The first cycle was double-blind and placebo-controlled with eligible patients randomized 1:1 to TOBI PODHALER (four 28-mg capsules twice daily) or placebo. For Cycles 2 and 3, patients who were initially randomized to placebo received TOBI PODHALER. Of the 79 patients included in the prespecified interim analysis, 18 were excluded due to a failure to meet spirometry quality review criteria, which resulted in a total of 61 patients included in the primary analysis.[1,5]

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.

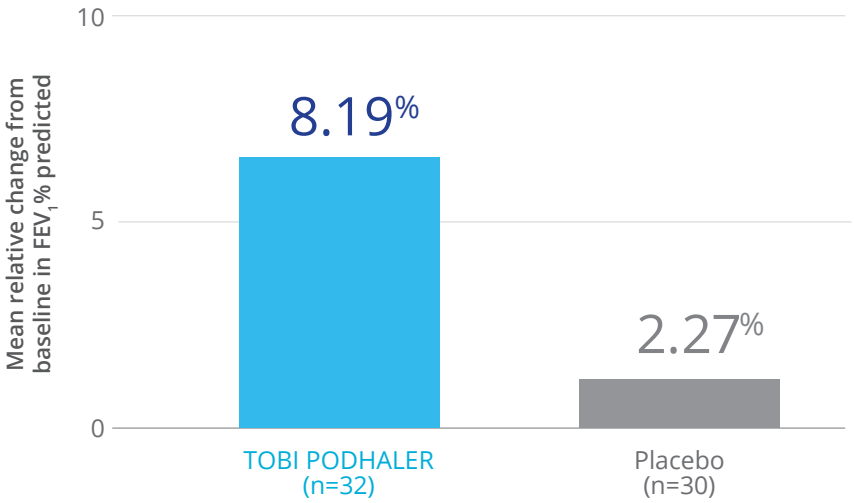
Please see additional Important Safety Information on page 22.

Click here for Full Prescribing Information.

In a separate placebo-controlled study,

Lung function was evaluated in patients treated with TOBI PODHALER *vs.* placebo[1]

Mean relative change in FEV_1% predicted from baseline to the end of first 28 days on treatment (*P*=0.167)



Primary endpoint in EDIT (Study 3)[1]

- Results not statistically significant[1]
- Mean absolute change in FEV_1% predicted was 4.86% for TOBI PODHALER and 0.48% for placebo, with a difference of 4.38% (95% CI: -0.17, 8.94)[1]

EDIT study design[1,6]

- EDIT was an 8-week, randomized, double-blind, placebo-controlled study in patients aged 6 to 21 years with CF, *Pa*, and FEV_1 ≥25% and ≤80% predicted at screening
- Patients with any use of inhaled antipseudomonal antibiotics within 4 months prior to screening were excluded
- Eligible patients were randomized 1:1 to receive TOBI PODHALER (4 times 28-mg capsules twice daily; n=32) or placebo (n=30) for 1 cycle (28 days on treatment and 28 days off treatment)
- The EDIT study was underpowered due to an inability to recruit the prespecified number of TOBI-naïve patients into each arm

Decreased susceptibility of *Pa* to tobramycin has been seen with use of TOBI PODHALER. The relationship between in vitro susceptibility test results and clinical outcome with TOBI PODHALER therapy is not clear. Occurrence of decreased susceptibility on treatment should be monitored, and treatment with an alternative therapy should be considered if clinical worsening is observed.[1]

EDIT, Establish tobramycin Dry powder efflcacy In cysTic fibrosis.

Please see additional Important Safety Information on page 22.
Click here for Full Prescribing Information.

Safety considerations for patients taking TOBI PODHALER

In a head-to-head study, TOBI PODHALER was evaluated for safety *vs.* TOBI® (Tobramycin Inhalation Solution, USP):[1]

Adverse reactions (≥10%)	TOBI PODHALER (n=308)	TOBI (n=209)
Cough	48.4%	31.1%
Lung disorders[a]	33.8%	30.1%
Productive cough	18.2%	19.6%
Dyspnea	15.6%	12.4%
Pyrexia	15.6%	12.4%
Oropharyngeal pain	14.0%	10.5%
Dysphonia	13.6%	3.8%
Hemoptysis	13.0%	12.4%
Headache	11.4%	12.0%

Discontinuations due to adverse events were higher in the TOBI PODHALER arm (14%) than in the TOBI arm (8%)[1]

EAGER: Establish A new Gold standard Efficacy and safety with tobramycin in cystic fibRosis.

[a]This includes adverse events of pulmonary or CF exacerbations.[1]

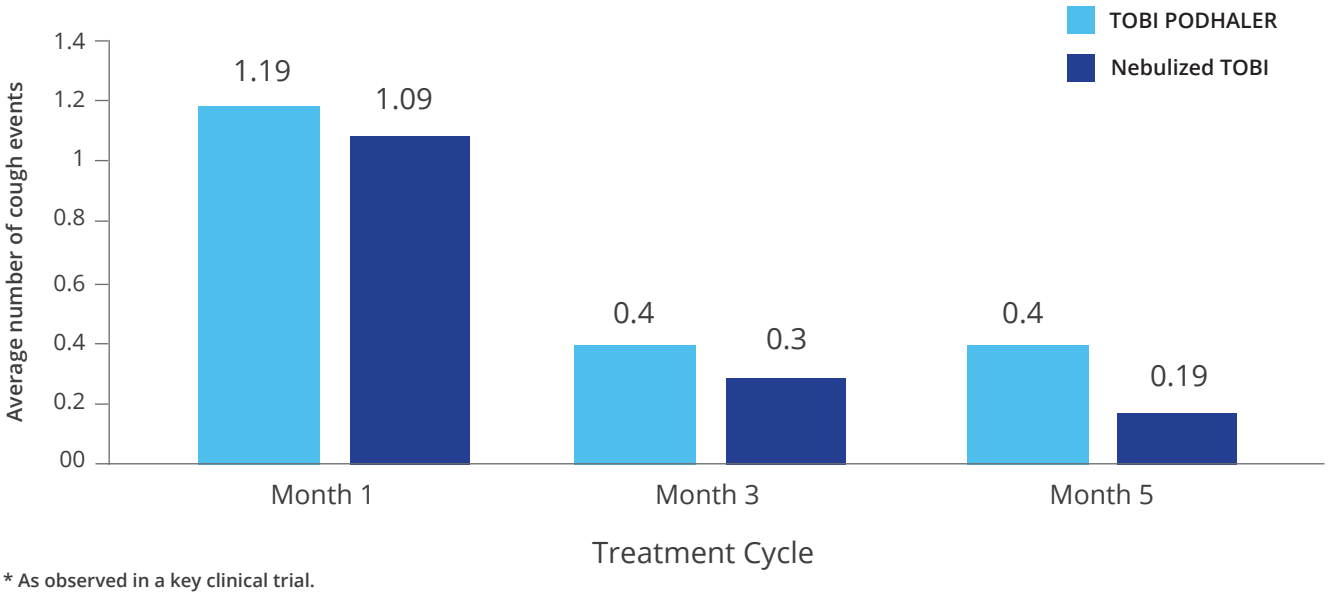
The EAGER study was a randomized, open-label, parallel-group study in 517 patients with CF and *Pa* (within 6 months of screening) aged ≥6 years with FEV_1 ≥25% to ≤75% predicted. The study consisted of 3 cycles; each cycle consisted of 28 days on treatment followed by 28 days off treatment, for a total duration of 24 weeks. Patients were randomized (3:2) to receive TOBI PODHALER 112 mg BID (n=308) or TOBI 300 mg/5 mL BID (n=209).[1,7]

Please see additional Important Safety Information on page 22.
Click here for Full Prescribing Information.

Managing cough With TOBI PODHALER

Cough is among the most common side effects of TOBI PODHALER but with the following information and tips, it can be managed effectively.

Cough events decrease over time with consistent use of TOBI PODHALER*



* As observed in a key clinical trial.

In a clinical trial evaluating the safety of TOBI PODHALER *vs.* TOBI nebulizer solution:[1]

- Patients using TOBI PODHALER, the dry-powder inhalation, experienced cough more frequently than patients using TOBI nebulizer solution (48% *vs.* 31%)
- After the first week of treatment, the time to first cough was similar for patients using TOBI Podhaler and TOBI nebulizer solution
- Five percent of patients using TOBI PODHALER discontinued due to cough compared with 1% of patients using TOBI nebulizer solution

Please see additional Important Safety Information on page 22.
Click here for Full Prescribing Information.

TOBI® Podhaler®
Tobramycin Inhalation Powder 28 mg per capsule

Helpful tips for using TOBI PODHALER

Patients and caregivers should be initially trained by their healthcare provider on the proper use of TOBI PODHALER.

1

PREPARATION

DO NOT press the blue button on the PODHALER device more than once, as the capsule may break into pieces if the button is pressed multiple times.[1]

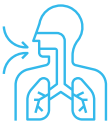
2

BEFORE USE

Tilt head up slightly when inhaling.

This helps straighten your throat out and provides the powder a more direct path to the lungs instead of hitting the back of the throat.[8]

3



DURING USE

Inhale deeply with an even medium speed.

This allows for a steady full inhalation of the powder. An inhalation that is too fast may send too much powder to the back of the throat. A slow inhalation may not fully empty the capsule.[1,8]

4

AFTER USE

Take a sip of water after inhaling each capsule.[1,8]

Watch a summary video on how to use TOBI PODHALER

IMPORTANCE OF TRAINING

Patients and caregivers should be initially trained by their CF Care Team on the proper use of TOBI PODHALER. In addition to live training, patients should be advised to read and understand the Patient Information and the Full Instructions for Use. Also be sure to watch the summary video on how to use TOBI PODHALER by visiting www.TOBIPODHALER.com or scanning the QR Code.

Please see additional Important Safety Information on page 22.
Click here for Full Prescribing Information.

Counseling TOBI PODHALER patients

Talk to your patients about what to expect

Acknowledge

- Cough is a common symptom of cystic fibrosis[1]
- In a clinical trial, patients taking TOBI PODHALER reported a higher incidence of cough than patients taking TOBI (Tobramycin Inhalation Solution, USP) during the first week of active treatment[1]

Educate

- After the first week of treatment in the same study, the time to first cough was similar in patients taking TOBI PODHALER and patients taking TOBI. Five percent of patients taking TOBI PODHALER discontinued due to cough compared with 1% of patients taking TOBI[1]

Train

- Patients and caregivers should be initially trained by their CF Care Team on the proper use of TOBI PODHALER[1]
- In addition to the training you provide your patients, advise patients to read the Patient Information and the Full Instructions for Use[1]

IMPORTANT SAFETY INFORMATION (Continued)

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.

Please see additional Important Safety Information on page 22.

Click here for Full Prescribing Information.

Packaging overview

Each 28 day supply of TOBI PODHALER package contains:[1]

- **4 weekly packs (28-day supply), each containing:**
  - 56 capsules (7 blister cards of 8 capsules). Each blister card contains 8 TOBI PODHALER capsules (4 capsules for inhalation in the morning and 4 capsules for inhalation in the evening)
  - 1 PODHALER device and its storage case
- **1 reserve PODHALER device (to be used if needed) and its storage case**

Please see additional Important Safety Information on page 22.
Click here for Full Prescribing Information.

Patient profile

TOBI PODHALER (Tobramycin Inhalation Powder)

Case Presentation

18 years/Male/50th percentile

First *Pa* diagnosis at age 10

FEV_1: 63%

Average hospitalizations ~1/year

- **Looking for ways to help decrease his treatment time**
- High school graduate moving away to college this year
- Believes existing nebulized treatment time will impact his busy class and extracurricular schedule

38 years/Female/18.1

First *Pa* diagnosis at age 15

FEV_1: 60%

Average hospitalizations ~1/year

- **Unable to take her treatments with her during her busy day**
- Works as a local wedding coordinator
- Difficulty fitting in all her daily treatments due to travel around town for work and her son's school commitments and sporting events

Please see additional Important Safety Information on page 22.
Click here for Full Prescribing Information.

Access and Adherence Resources

PODMANAGER®

An app designed specifically for people with CF that helps them manage their treatment regimen

Track, view, and analyze adherence data to better understand overall treatment regimens

Helps promote accountability through customizable treatment reminders for your medications

Helpful training resources for TOBI PODHALER (tobramycin inhalation powder)

Information for **support programs** such as PODCARE+® and the TOBI PODHALER Savings Card

Air Quality Information

- Real-time air quality alerts deliver a convenient update about the current outside environment based on the user's location
- Air Quality Index measurements are based on hourly readings for your location

TOBI PODHALER Resources

- Educational content focused on proper use of TOBI PODHALER
- View step-by-step video instructions on administration
  - How to prepare the first dose
  - Loading the capsule
  - Complete dosing and aftercare
- Information for TOBI PODHALER patient support programs such as PODCARE+ and Savings Card signup

Download the App

GET IT ON Google Play

Available on the App Store

TOBI® Podhaler®
Tobramycin Inhalation Powder 28 mg per capsule

PODMANAGER

An app designed specifically for people with CF that helps them manage their treatment regimen

Customizable Treatment Reminders and Adherence Analytics

Set up treatment reminders for your patient's medications or activities to focus on accurate adherence with CF treatment regimens

Allows for full customization based on dosing frequency so that the app can deliver accurate reminders throughout the user's day, week, month

Treatment tracking function allows the user to record each time they have taken a dose, completed a treatment, or finished an activity

Adherence data is compiled and displayed in graphs, charts, and calendars to see proficiency with their overall CF treatment regimen

Learn More about PODMANAGER at **TOBIPODHALERHCP.com**

Expanded patient access and coverage

TOBI PODHALER
is COVERED for over

83%

of Commercial and Medicaid Insurance plans combined nationwide*

TOBI PODHALER is NOW

PREFERRED BRAND on **Express Scripts** National Commercial Formularies.*

COVERED on **Cigna** commercial insurance plans.

COVERED on **OptumRx** National Commercial Formularies.*

COVERED on **United Health Care** National Commercial Formularies.*

*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.

Patient resources for access

podcare+®

PODCARE+ performs a variety of support services based on individual patient 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 access to medication

Electronic PA Support

Seamless integration with CoverMyMeds® to efficiently coordinate PA process

Savings Card

Eligible commercially insured patients may pay as little as $0 for their TOBI PODHALER prescription. Terms, conditions, and limitations apply*

Enroll Your Patient in PODCARE+ by

Visiting TOBIPODHALERHCP.com to download an enrollment form

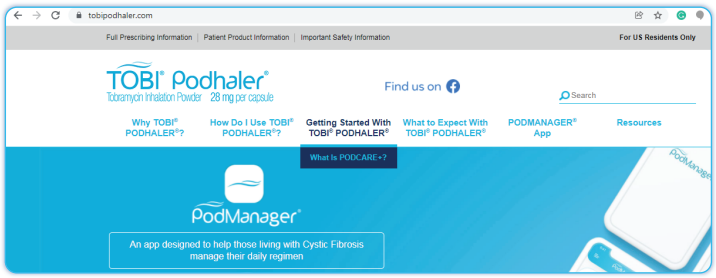
Calling The PODCARE+ Hotline, 1-877-999-TOBI (8624). Available Monday through Friday, 8 am to 8 pm ET.

If eligible, commercially insured patients want to only enroll in the TOBI PODHALER Savings Card Program, visit www.ActivateTheCard.com/TOBI

*This Savings Card may be used to reduce the amount of an 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. 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. 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 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, 2023. For full terms and conditions, visit www.activatethecard.com/tobi.

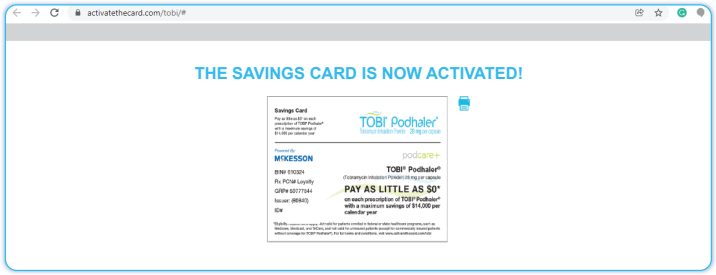
Savings Card Program

- Eligible commercially insured patients may access the TOBI PODHALER Savings Program by **signing up on TOBIPODHALER.com** in the "What is PODCARE+?" section under the Getting Started With TOBI PODHALER tab



- Patients/HCP/caregivers may enroll to TOBI PODHALER Savings Program by **clicking on their specific product and completing a simple form**

- Eligible patients will receive their **Savings Card* information on the next screen so that the information can be printed and/or captured.** This information should be shared with the pharmacy that is dispensing the TOBI PODHALER prescription



*This Savings Card may be used to reduce the amount of an 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. 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. 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 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, 2023. For full terms and conditions, visit www.activatethecard.com/tobi.

TOBI® Podhaler®
Tobramycin Inhalation Powder 28 mg per capsule

INDICATION and IMPORTANT SAFETY INFORMATION

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.

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.

Notes

TOBI® Podhaler®

Tobramycin Inhalation Powder 28 mg per capsule

References:

1. Prescribing information. TOBI® PODHALER®. October 2020. Available at: https://dailymed.nlm.nih.gov/dailymed/fda/fdaDrugXsl.cfm?setid=c4b5bb1f-e158-4ac1-9c35-e98a416c743a&type=display. Accessed on February 01, 2022.
2. Geller DE, Weers J, Heuerding S. Development of an inhaled dry-powder formulation of tobramycin using PulmoSphere® Technology. *J Aerosol Med Pulm Drug Deliv*. 2011;24(4):175-182.
3. Tiddens HA, Geller DE, Challoner P, *et al.* Effect of dry powder inhaler resistance on the inspiratory flow rates and volumes of cystic fibrosis patients of six years and older. *J Aerosol Med.* 2006;19(4):456-465.
4. Data on file [TSB-001 The inspiratory volume and flow of cystic fibrosis patients while using a simulated dry powder inhaler]. Mylan Specialty L.P.; 2003.
5. Konstan MW, Geller DE, Minic P, Brockhaus F, Zhang J, Angyalosi G. Tobramycin inhalation powder for *P. aeruginosa* infection in cystic fibrosis: the EVOLVE trial. *Pediatr Pulmonol*. 2011;46(3):230-238.
6. Galeva I, Konstan MW, Higgins M, *et al.* Tobramycin inhalation powder manufactured by improved process in cystic fibrosis: the randomized EDIT trial. *Curr Med Res Opin.* 2013;29(8):947-956.
7. Konstan MW, Flume PA, Kappler M, *et al.* Safety, efficacy and convenience of tobramycin inhalation powder in cystic fibrosis patients: the EAGER trial. *J Cyst Fibros.* 2011;10(1):54-61.
8. Data on file [Expert consultation with David E. Geller, MD; April 19, 2013].

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