

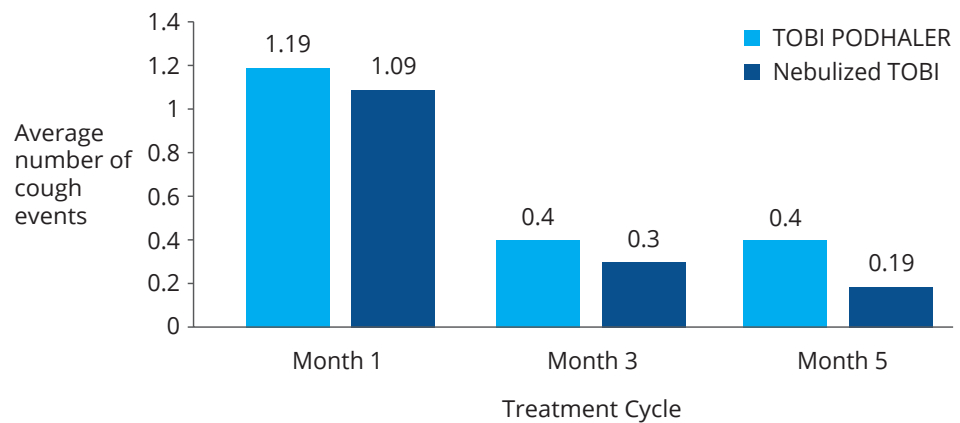
TOBI® PODHALER®: Managing Cough

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



Not actual size

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:

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.

INDICATION

TOBI® PODHALER® (Tobramycin Inhalation Powder) 28 mg per capsule is a prescription inhaled medication for cystic fibrosis patients whose lungs contain bacteria called *Pseudomonas aeruginosa*.

It is not known if TOBI PODHALER is safe and effective in patients under 6 years of age, in those with lung function outside of a certain range, or in those whose lungs contain bacteria called *Burkholderia cepacia*.

IMPORTANT SAFETY INFORMATION

Do not swallow TOBI PODHALER capsules. TOBI PODHALER capsules are used only with the Podhaler device and inhaled through your mouth (oral inhalation). Never place a capsule in the mouthpiece of the Podhaler device.

Please see accompanying [Full Prescribing Information](#) and [Patient Information](#). See reverse side for additional Important Safety Information.

How Do I Use TOBI PODHALER?

Your healthcare provider should show you or your caregiver how to use TOBI PODHALER before you use it for the first time.

The recommended dosage of TOBI PODHALER

4

28-mg capsules
for inhalation

2

times a day (AM
and PM) in cycles of

28

days
on and

28

days off

Important Dosing Considerations

- One treatment cycle consists of 28 days on and 28 days off treatment
- 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
- 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
- Capsules are for use with the PODHALER device only
- TOBI PODHALER capsules must not be swallowed and are for oral inhalation only
- Capsules should always be stored in the blister card; each capsule should only be removed IMMEDIATELY BEFORE USE
- The PODHALER device should always be stored in its case and tightly closed when not in use
- When starting a new weekly pack of capsules, use a new PODHALER device and storage case and discard the previous week's device and its case

IMPORTANT SAFETY INFORMATION (Continued)

You should not use TOBI PODHALER if you are allergic to it or to any other aminoglycoside antibacterial medicines.

Tell your doctor before starting treatment all of your medical conditions, including if you have or have had hearing problems, dizziness, kidney problems, muscle weakness, breathing problems such as wheezing, coughing or chest tightness, if you had an organ transplant, are pregnant or nursing or plan to become pregnant or nurse.

TOBI PODHALER contains a medicine that can harm your unborn baby. It is not known if it passes into breast milk. Check your baby for watery stools, bloody stools, thrush or diaper rash if you breast feed.

Tell your doctor about all the medicines you take including over-the-counter medicines, vitamins, and herbal supplements. If you are using TOBI PODHALER, discuss if you should take other medicines that may harm your nervous system, kidneys, or hearing; "water pills" (diuretics) such as EDECRIN® (ethacrynic acid), LASIX® (furosemide), or intravenous mannitol; urea.

TOBI PODHALER can cause **serious side effects**, including:

Severe breathing problems (bronchospasm). Tell your doctor right away if you get shortness of breath with wheezing or coughing and chest tightness while using TOBI PODHALER.

Hearing loss or ringing in the ears (ototoxicity). Tell your doctor right away if you have hearing loss, noises in your ears such as ringing or hissing, vertigo, difficulty with balance, dizziness, or your mother has had hearing problems after taking an aminoglycoside. Tell your doctor if you have been told you have certain gene variants (a change in the gene) related to hearing abnormalities inherited from your mother.

Helpful Tips For Using 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.

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.

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.

4

After Use



Take a sip of water after inhaling each capsule.

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.



IMPORTANT SAFETY INFORMATION (Continued)

Worsening kidney problems (nephrotoxicity). TOBI PODHALER is in a class of medicines that may cause worsening kidney problems, especially in people with known or suspected kidney problems. Your healthcare provider may do a blood test to check how your kidneys are working while you are using TOBI PODHALER.

Worsening muscle weakness. TOBI PODHALER is in a class of medicines that can cause worsening muscle weakness in people who already have problems with muscle weakness (myasthenia gravis or Parkinson's disease).

TOBI PODHALER is in a class of medicines which may cause harm to an unborn baby.

The most common side effects of TOBI PODHALER include cough, worsening of lung problems or cystic fibrosis, productive cough, shortness of breath, fever, sore throat, changes in your voice (hoarseness), coughing up blood, and headache.

Let your doctor know if your symptoms worsen or if you have a side effect that bothers you enough to stop treatment or that does not go away.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

Please see accompanying [Full Prescribing Information](#) and [Patient Information](#).

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