



Your World in **3D**  
Drug. Device. Delivered.



**Distributed by:**

PARI Respiratory Equipment, Inc.  
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# Kitabis<sup>®</sup> Pak

Tobramycin Inhalation Solution, USP

Drug. Device. Delivered.

## PATIENT GUIDE

SEE IMPORTANT SAFETY INFORMATION ON PAGES 11-12



PLEASE SEE ACCOMPANYING FULL PRESCRIBING INFORMATION AND PATIENT PRODUCT INFORMATION IN THIS BROCHURE.



## Kitabis<sup>®</sup> Pak, the first FDA Approved Convenience Kit with Nebulized Tobramycin.

- Kitabis<sup>®</sup> Pak (Ki TAH biss Pak) is a co-packaging of Tobramycin Inhalation Solution (drug) and PARI LC PLUS<sup>®</sup> Reusable Nebulizer (device) in a patient convenience kit.
- Kitabis Pak is indicated for the management of cystic fibrosis in adults and pediatric patients 6 years of age and older with P. aeruginosa.
- Safety and efficacy have not been demonstrated in patients under the age of 6 years, patients with FEV1 <25% or >75% predicted, or patients colonized with Burkholderia cepacia.
- Kitabis Pak also includes a PARI LC PLUS, the nebulizer handset used exclusively in clinical trials for Tobramycin Inhalation Solution. It is the only nebulizer approved by the FDA to safely and effectively deliver Tobramycin Inhalation Solution. One prescription, one stop.

**Drug. Device. Delivered.**

## Kitabis Pak Overview

Kitabis Pak includes a prescription medicine, Tobramycin Inhalation Solution, prescribed by your healthcare provider to treat adults and children 6 years of age and older with cystic fibrosis who have a bacterial infection called *Pseudomonas aeruginosa* (soo-doh-MOH-nass ah-ru-ji-NOH-sa) or *P. aeruginosa*. It is not known if Kitabis Pak is safe and effective in children under the age of 6, in people who have lung function of FEV<sub>1</sub> less than 25 % or more than 75% predicted, in people who have a lung infection with *Burkholderia cepacia* bacteria, or when used for more than 3 cycles.

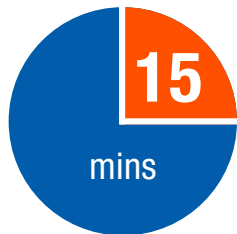
**CONTRAINDICATION:** DO NOT USE KITABIS PAK IF YOU ARE ALLERGIC TO TOBRAMYCIN, ANY OF THE INGREDIENTS IN KITABIS PAK, OR TO ANY OTHER AMINOGLYCOSIDE ANTIBACTERIAL MEDICINE.



## The treatment schedule for Kitabis Pak is as follows<sup>1</sup>:



2 times a day



Approximately **15**  
minute nebulization time



28 days **on**, then  
28 days **off**

### Take Kitabis Pak:

- One single-use ampule (300mg /5mL) twice a day by oral inhalation
- As close to 12 hours apart as possible, and not less than 6 hours apart
- In alternating 28 days on drug, followed by 28 days off drug

It is not known if Kitabis Pak is safe and effective when used for more than 3 cycles.

<sup>1</sup>Kitabis Pak [package insert]. Midlothian, VA: PARI Respiratory Equipment, Inc; 2014.

# KITABIS PAK CONTENTS

Tobramycin Inhalation Solution Carton



56 Ampules (Vials)

14 Foil Pouches



PARI LC PLUS  
Reusable Nebulizer



Wing Tip® tubing

PARI LC PLUS  
Instructions For Use



Kitabis Pak Package  
Insert, Patient Information,  
Patient Instructions



## Storing your Kitabis Pak

- Store Tobramycin Inhalation Solution in the refrigerator between 36°F to 46°F (2°C to 8°C) until needed. The PARI LC PLUS does not need to be refrigerated.
- Do not use Tobramycin Inhalation Solution if it has been stored at room temperature (up to 25°C/77°F) for more than 28 days.
- Keep Tobramycin Inhalation Solution in the foil pouch and out of the light.
- Do not use Tobramycin Inhalation Solution after the expiration date stamped on the ampule.

- Do not use Tobramycin Inhalation Solution if it is cloudy, has particles in the solution, or if it has been stored at room temperature for more than 28 days. Throw the applicable ampule(s) away in the household trash and get a new ampule.

## Unrefrigerated Tobramycin Inhalation Solution

When you don't have a refrigerator available (for example, when you are traveling), you may store the Tobramycin Inhalation Solution pouches (opened or unopened) at room temperature (up to 25°C/77°F) for up to 28 days. Tobramycin Inhalation Solution is normally slightly yellow, but may get darker with age if unrefrigerated. The color change does not change how the medicine works.



## Nebulizer Choice Matters In Inhaled Tobramycin Delivery

- There are important differences in delivered tobramycin doses among nebulizer brands.<sup>3</sup>
- Tobramycin Inhalation Solution (TIS) was specifically formulated for use with the PARI LC PLUS®.<sup>3,4</sup>
- The PARI LC PLUS is a breath-enhanced nebulizer that generates less medication waste, consistent particle size, and fast nebulization.<sup>5</sup>

<sup>3</sup>Vecellio L, Abdelrahim ME, Montharu J et al., Disposable versus reusable jet nebulizers for cystic fibrosis treatment with tobramycin. *J Cys Fibros*. 2011;10: 86–92.

<sup>4</sup>Ramsey BW, Pepe MS, Quan JM et al. Intermittent administration of inhaled tobramycin in patients with cystic fibrosis. *Cystic Fibrosis Inhaled Tobramycin Study Group. N Engl J Med*. 1999;340:23-30.

<sup>5</sup>Data on file

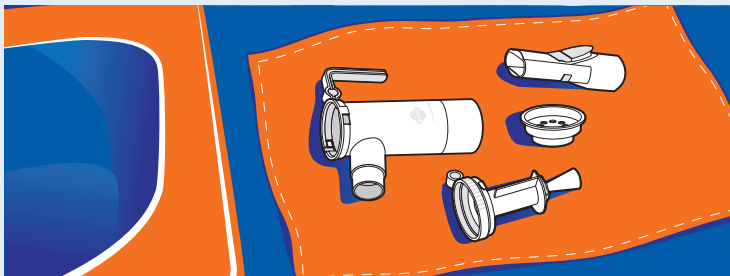


# Care of Nebulizers: An Important Step in Preventing Infection

## Clean After Every Treatment

**Dishwasher safe!** *(top rack)*

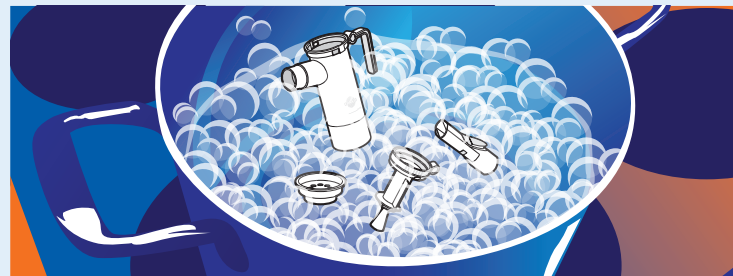
Clean thoroughly with dish soap and water, or dishwasher, at the end of every treatment. Air dry on lint free cloth.



*DO NOT WASH TUBING*

You must regularly disinfect or sterilize the nebulizer between treatments.

All parts (except tubing and mask) may be disinfected by boiling them in a clean pot of water for a full 5 minutes.



*IMPORTANT: See Instructions for Use for full cleaning and disinfection instructions*

PLEASE SEE ACCOMPANYING FULL PRESCRIBING INFORMATION AND PATIENT PRODUCT INFORMATION IN THIS BROCHURE.

## Common Questions About Kitabis Pak

### 1. What do I do if a dose of Tobramycin Inhalation Solution is missed?

Never double a dose to make up what was missed. Tobramycin Inhalation Solution should be inhaled twice a day as close to 12 hours apart as possible and not less than 6 hours apart. A missed dose can be taken later than planned as long as it is at least 6 hours before the next dose. After taking your missed dose, go back to your regular dosing schedule.

### 2. Should I or my child stop taking Tobramycin Inhalation Solution if feeling better?

**No.** Tobramycin Inhalation Solution should be taken twice a day by oral inhalation for 28 days, followed by 28 days off drug.

### 3. Can Tobramycin Inhalation Solution be mixed with other inhaled medications?

**No.** Tobramycin Inhalation Solution should not be mixed with any other medicine, including dornase alfa (Pulmozyme®).

### 4. Can I use part of my Tobramycin Inhalation Solution ampule and save the rest for later?

**No.** Tobramycin Inhalation Solution comes in sterile, single-use ampules that should be used completely.



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#### 5. Should Tobramycin Inhalation Solution be taken with or without food?

Tobramycin Inhalation Solution can be taken before or after eating. However, if it causes coughing, you may wish to take Tobramycin Inhalation Solution before eating or 2 hours after eating.

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#### 6. Can I use PARI LC PLUS from the Kitabis Pak for other drugs?

**Yes.** However, it is best to use the PARI LC PLUS included with Kitabis Pak only for the Tobramycin Inhalation Solution included with your pak.

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#### 7. Does Tobramycin Inhalation Solution expire?

**Yes.** There are expiration dates stamped on each ampule. It is important to follow the stamped date and discard any ampules that expire.

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#### 8. Is there insurance coverage for Kitabis Pak?

**Yes.** Kitabis Pak is covered on most state Medicaid PDL programs as well as having excellent commercial coverage. See [www.kitabis.com/patient-access](http://www.kitabis.com/patient-access) for more information.

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#### 9. Are there any patient support programs available?

**Yes.** Co-Pay assistance is available for eligible patients. With commercial insurance, patients may be eligible to pay as little as \$0 per prescription through the Kitabis Pak Co-Pay Assistance Program. \*Eligibility restrictions apply.

## Important Safety Information About Kitabis Pak

Do not take Kitabis Pak (Tobramycin Inhalation Solution) if you are allergic to tobramycin, or any of the ingredients in Kitabis Pak, or any aminoglycoside antibiotic.

Before taking Kitabis Pak, inform your health care provider if you have or have had any hearing problems (including noises in your ears such as ringing or hissing), hearing loss, your mother has had hearing problems after taking an aminoglycoside, you have been told you have certain gene variants related to hearing abnormalities inherited from your mother, dizziness, kidney problems, muscle weakness such as myasthenia gravis or Parkinson's disease, breathing problems such as wheezing, coughing or chest tightness, or have had an organ transplant. Before you inhale Kitabis Pak, inform your health care provider if you are pregnant, plan to become pregnant, are breastfeeding, or plan to breastfeed. It is not known if Kitabis Pak will pass into breast milk.

Tell your health care provider about all the medicines you take. Taking Kitabis Pak with certain other medications can cause serious side effects. If you are taking Kitabis Pak, you should discuss with your health care provider if you should take other medicines that may harm your nervous system, kidneys or hearing, or diuretics (water pills) such as Edecrin® (ethacrynic acid), Lasix® (furosemide), mannitol, or urea.

## Important Safety Information About Kitabis Pak

Kitabis Pak can cause serious side effects including hearing loss or ringing in the ears (ototoxicity), worsening kidney problems (nephrotoxicity), worsening muscle weakness, harm to an unborn baby, and/or severe breathing problems (bronchospasm). Tell your health care provider right away if you have hearing loss or hear noises in your ears (such as ringing or hissing), develop vertigo, dizziness, difficulty with balance, shortness of breath with wheezing, or coughing or chest tightness. Your health care provider may do a blood test and urine test to check how your kidneys are working while you are taking Kitabis Pak.

Most Common Side Effects of Kitabis Pak include:

- **Cough**
- **Sore throat**
- **Productive cough**
- **Shortness of breath**
- **Coughing up blood**
- **Worsening of lung problems or cystic fibrosis**
- **Changes in your voice (hoarseness)**
- **Altered taste**
- **Rash**

Call your doctor for medical advice about side effects.

You may report side effects to FDA at **1-800-FDA-1088** or **[www.fda.gov/medwatch](http://www.fda.gov/medwatch)**

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## About **PARI**

*There aren't many companies like PARI. Over 100 years in existence, 50 years selling nebulizers worldwide, and 20 years formulating nebulized medications.*

PARI products are designed **with our patients in mind**, providing efficient aerosol therapy (drug + device) in order to improve the lives of nebulizer patients and their families. PARI's identity includes a strong clinical track record earned through years of clinical research, and through proven safety and efficacy with well-known nebulized medications for patients with asthma, COPD and cystic fibrosis.

