



# Tobramycin Inhalation (Kitabis™) Abbreviated New Drug Update

---

## OVERVIEW<sup>1</sup>

- Tobramycin inhalation solution indicated for:
  - ❑ Management of cystic fibrosis (CF) in adults and pediatric patients six years of age and older with *Pseudomonas aeruginosa*.
- Kitabis™ Pak is a co-packaging of Tobramycin Inhalation Solution and a PARI LC PLUS® nebulizer handset in one convenient kit.
- Availability
  - ❑ Drug: 56 Single-Use Ampules (28-Day Supply) [14 foil pouches-each with 4 Single-Use Ampules]
  - ❑ Device: One PARI LC PLUS Reusable Nebulizer
- Dosage
  - ❑ One single-use ampule (300 mg /5 mL) of tobramycin inhalation solution twice a day by oral inhalation in alternating periods of 28 days on drug, followed by 28 days off drug.
  - ❑ The 300 mg/5 mL dose of tobramycin inhalation solution is the same for all patients regardless of age or weight.
- Each dose of tobramycin inhalation solution is administered by oral inhalation using only the copackaged PARI LC PLUS Reusable Nebulizer (Model No. 022B81-T) included in the Kitabis Pak, along with a DeVilbiss Pulmo-Aide air compressor (Model No. 5650D).
- The entire tobramycin inhalation solution treatment should take approximately 15 minutes to complete with an average treatment time of six to seven minutes.<sup>2</sup>
- PARI LC PLUS Reusable Nebulizer is reusable for up to six months, and is easily sanitized via boiling, dishwasher, or autoclave.<sup>3</sup>

- The safety and efficacy of Kitabis Pak was demonstrated in two identically designed, double-blind, randomized, placebo-controlled, parallel group, 24-week clinical studies at a total of 69 CF centers in the United States.
  - ❑ In these clinical studies, 258 patients received tobramycin inhalation solution therapy on an outpatient basis using a PARI LC PLUS nebulizer along with a DeVilbiss Pulmo-Aide compressor.
  - ❑ In Study 1, tobramycin inhalation solution-treated patients had an average increase in FEV<sub>1</sub> % predicted of about 11% relative to baseline (Week 0) during 24 weeks compared to no average change in placebo patients.
  - ❑ In Study 2, tobramycin inhalation solution-treated patients had an average increase of about 7% compared to an average decrease of about 1% in placebo patients over 24 weeks.

## CLINICAL CONSIDERATIONS

- The 2013 CF Pulmonary Clinical Practice Guidelines concluded that inhaled tobramycin for moderate to severe disease (recommendation A), inhaled tobramycin for mild disease (recommendation B), inhaled aztreonam for moderate to severe disease (recommendation A), and inhaled aztreonam for mild disease (recommendation B), were effective treatments for *P. aeruginosa* in patients with CF.<sup>4</sup>
- There are several brands of tobramycin inhalation solution available to treat patients with CF including Kitabis, Bethkis®, Tobi®, and generics. Aztreonam for inhalation solution (Cayston®) is also approved for management of patients with CF.
- Kitabis is the only tobramycin inhalation solution available which is also co-packaged with a nebulizer.
- Notable differences among the products included method of administration (nebulization [Cayston, TOBI, Kitabis, and Bethkis] versus handheld device [TOBI Podhaler]); frequency of administration (twice daily [TOBI, TOBI Podhaler, Kitabis and Bethkis] versus three times daily [Cayston]); duration of administration (two to three minutes per treatment [Cayston] versus approximately 15 minutes per treatment [TOBI, Kitabis, and Bethkis] versus two to seven minutes per treatment [TOBI Podhaler; result from clinical study]); FDA-approved ages (six years and older [TOBI, TOBI Podhaler, Kitabis, and Bethkis] versus seven years and older [Cayston]); reconstitution requirements (reconstitution needed [Cayston] versus no reconstitution needed [TOBI, TOBI Podhaler, Kitabis, and Bethkis]); and packaging (medication plus nebulizer [Kitabis] versus medication alone [TOBI, Bethkis, and Cayston]).

## REFERENCES

<sup>1</sup> Kitabis [package insert]. Woodstock, IL; Catalent Pharma Solutions; November 2014.

<sup>2</sup> PARI Respiratory Equipment, Inc. - Product - LC PLUS® Reusable Nebulizer - Performance Data. (2015, January 9). Retrieved from [http://www.pari.com/products/nebulizers/product/detail/info/techdata/lc\\_plus\\_reusable\\_nebulizer.html](http://www.pari.com/products/nebulizers/product/detail/info/techdata/lc_plus_reusable_nebulizer.html)

<sup>3</sup> PARI LC PLUS Reusable Nebulizer [package insert]. Midlothian, VA; PARI Respiratory Equipment, Inc.; July 2010. Retrieved from [http://www.pari.com/fileadmin/user\\_upload/PARI.com\\_Amerika/Instructions/022D0121\\_LC\\_Plus\\_Star\\_IFU\\_EN\\_ES.pdf](http://www.pari.com/fileadmin/user_upload/PARI.com_Amerika/Instructions/022D0121_LC_Plus_Star_IFU_EN_ES.pdf)

<sup>4</sup> Mogayzel, PJ, Naureckas ET, Robinson KA, et. al. Cystic Fibrosis Pulmonary Guidelines. Chronic medications for maintenance of lung health. Am J Respir Crit Care Med. 2013; 187(7): 680-689.