Tobramycin Inhalation Solution, USP 300 mg/5 mL is indicated for the management of cystic fibrosis patients with exacerbations of bronchiectasis due to Pseudomonas aeruginosa. For patients with cystic fibrosis, the susceptibility test results and clinical outcome with tobramycin inhalation solution therapy is not clear. Studies have shown that susceptibility testing for Pseudomonas aeruginosa isolates from patients with cystic fibrosis can have many symptoms. If you are taking several medications, some of these symptoms may be related to your medications. It is important that your nebulizer and compressor be clean. You should store tobramycin inhalation solution ampules in a refrigerator (2° to 8°C or 36° to 46°F). When you don't have a refrigerator available (e.g., transporting your tobramycin inhalation solution beyond the expiration date stamped on the ampule). Additional Information

Use Only

Nebulizer Formulation

Tobramycin inhalation solution, USP 300 mg/5 mL is a yellow, non-pyrogenic, aqueous solution with the pH and salinity adjusted specifically for administration by nebulization. All ingredients meet USP requirements. The formulation contains no preservatives.

Susceptibility Testing

Tobramycin exhibits in vitro activity against a wide range of gram-negative organisms including Pseudomonas aeruginosa, other aminoglycoside-resistant pseudomonads, and other pseudomonads.MIC values and monitoring for the development of resistance is recommended.

Dosage

1. Turn on the compressor.
2. Wipe outside of the compressor cabinet with a clean, damp cloth every few days to keep dust free.
3. Lay out the contents of a PARI LC PLUS™ Reusable Nebulizer package on a clean, dry paper or cloth towel. You should have the nebulizer solution, nebulizer, tubing, nebulizer cup, nebulizer top and bottom, air compressor, and paper or cloth towels. The tubing should fit snugly. Plug in your air compressor and PARI LC PLUS™ Nebulizer and turn on the nebulizer. You will need the following supplies:

- Tobramycin inhalation solution (plain or adçet stump)
- Nebulizer
- Tubing to connect the nebulizer and compressor
- Clean paper or cloth towels
- Nose clips may help you breathe through your mouth and not through your nose. Do not block your mouth. Nose clips may help you breathe through your mouth and not through your nose. Do not block your mouth.

4. Open the tobramycin inhalation solution ampule by holding the Ampule Handle with one hand and the Ampule Cap with the other hand. Be careful not to squeeze the ampule. Ampules contain approximately 1.5 mL of solution. You should take tobramycin inhalation solution in repeated cycles of 28 days on drug followed by 28 days off drug. You will not be exposed to the tobramycin inhalation solution for 2 of every 7 days. Although some patients have been exposed to 2 days of tobramycin inhalation solution therapy.

Treatment Schedule

You should take your tobramycin inhalation solution in repeated cycles of 28 days on drug followed by 28 days off drug. You will not be exposed to the tobramycin inhalation solution for 2 of every 7 days. Although some patients have been exposed to 2 days of tobramycin inhalation solution therapy.

How To Administer Tobramycin Inhalation Solution for Inhalation

1. Clean the nebulizer and compressor. Tobramycin inhalation solution can be taken in a single dose, ready-to-use ampule or in a multiple-dose foil pouch. A multiple-dose foil pouch contains 4 ampules.

2. Squeeze the patients. If you want to become pregnant or are pregnant while on tobramycin inhalation solution, you should inform your physician and CF care team about properly taking in a single dose, ready-to-use ampule or in a multiple-dose foil pouch. A multiple-dose foil pouch contains 4 ampules.

3. Squeeze the patients. If you want to become pregnant or are pregnant while on tobramycin inhalation solution, you should inform your physician and CF care team about properly taking in a single dose, ready-to-use ampule or in a multiple-dose foil pouch. A multiple-dose foil pouch contains 4 ampules.
Top into the Nebulizer Cup, the In order to insert the Nebulizer 3. Sit or stand in an upright position Treatment the Air Intake firmly. Inspiratory Valve Cap in place on the Nebulizer Outlet. Then firmly push the 9. Attach the Nebulizer Tubing. This should point push the Inspiratory Valve Cap into the Nebulizer Cup. 

Cleaning Your Nebulizer 1. Rinse the component 2. Check to make sure that all tubing connections and confirm that the compressor is not leaking. 3. Sit or stand in an upright position that will breathe normally.
Tobramycin (toe-bra-MYE-sin) Inhalation Solution, USP
Nebulizer Solution — For Inhalation Use Only

Information for Patients

Safety Information
Tobramycin inhalation solution is in a class of antibiotics that have caused hearing loss, dizziness, kidney damage and harm to a fetus. Ringing in the ears and hoarseness were two symptoms that were seen in more patients taking tobramycin inhalation solution than placebo in research studies. Patients with cystic fibrosis can have many symptoms. Some of these symptoms may be related to your medications. If you have new or worsening symptoms, you should tell your doctor.

Hearing: You should tell your doctor if you have ringing in the ears, dizziness, or any changes in hearing.

Kidney Damage: Inform your doctor if you have any history of kidney problems.

Pregnancy: If you want to become pregnant or are pregnant while on tobramycin inhalation solution, you should talk with your doctor about the possibility of tobramycin inhalation solution causing any harm.

Nursing Mothers: If you are nursing a baby, you should talk with your doctor before using tobramycin inhalation solution.

Tobramycin Inhalation Solution Packaging
Tobramycin inhalation solution comes in a single dose, ready-to-use ampule containing 300 mg tobramycin. Each foil pouch contains 4 ampules, for 2 days of tobramycin inhalation solution therapy.

Dosage
The 300 mg dose of tobramycin inhalation solution is the same for patients regardless of age or weight. Tobramycin inhalation solution has not been studied in patients less than 6 years old. Doses should be inhaled as close to 12 hours apart as possible and not less than six hours apart. You should not mix tobramycin inhalation solution with dornase alfa (PULMOZYME®, Genentech) in the nebulizer.

Treatment Schedule
You should take tobramycin inhalation solution in repeated cycles of 28 days on drug followed by 28 days off drug. You should take tobramycin inhalation solution twice a day during the 28-day period on drug.

How To Administer Tobramycin Inhalation Solution for Inhalation

THIS INFORMATION IS NOT INTENDED TO REPLACE CONSULTATION WITH YOUR PHYSICIAN AND CF CARE TEAM ABOUT PROPERLY TAKING MEDICATION OR USING INHALATION EQUIPMENT.

Tobramycin inhalation solution is specifically formulated for inhalation using a PARI LC PLUS™ Reusable Nebulizer and a DeVilbiss® Pulmo-Aide® air compressor. Tobramycin inhalation solution can be taken at home, school, or at work. The following are instructions on how to use the DeVilbiss® Pulmo-Aide® air compressor and PARI LC PLUS™ Reusable Nebulizer to administer Tobramycin Inhalation Solution for Inhalation.

You will need the following supplies:
- Tobramycin inhalation solution plastic ampule (vial)
- DeVilbiss® Pulmo-Aide® air compressor
- PARI LC PLUS™ Reusable Nebulizer
- Tubing to connect the nebulizer and compressor
- Clean paper or cloth towels
- Nose clips (optional)

It is important that your nebulizer and compressor function properly before starting your tobramycin inhalation solution therapy.

Note: Please refer to the manufacturers’ care and use instructions for important information.

Preparing Your Tobramycin Inhalation Solution for Inhalation

1. Wash your hands thoroughly with soap and water.

2a. Tobramycin inhalation solution is packaged with 4 ampules per foil pouch.

2b. Separate one ampule by gently pulling apart at the bottom tabs. Store all remaining ampules in the refrigerator as directed.

3. Lay out the contents of a PARI LC PLUS™ Reusable Nebulizer package on a clean, dry paper or cloth towel. You should have the following parts:
- Nebulizer Top and Bottom (Nebulizer Cup) Assembly
- Inspiratory Valve Cap
- Mouthpiece with Valve
- Tubing

4. Remove the Nebulizer Top from the Nebulizer Cup by twisting the Nebulizer Top counterclockwise, and then lifting. Place the Nebulizer Top on the clean paper or cloth towel. Stand the Nebulizer Cup upright on the towel.

5. Connect one end of the tubing to the compressor air outlet. The tubing should fit snugly. Plug in your compressor to an electrical outlet.

6. Open the tobramycin inhalation solution ampule by holding the bottom tab with one hand and twisting off the top of the ampule with the other hand. Be careful not to squeeze the ampule until you are ready to empty its contents into the Nebulizer Cup.
1. Turn on the compressor.

2. Check for a steady mist from the Mouthpiece. If there is no mist, check all tubing connections and confirm that the compressor is working properly.

3. Sit or stand in an upright position that will allow you to breathe normally.

4. Place Mouthpiece between your teeth and on top of your tongue and breathe normally only through your mouth. Nose clips may help you breathe through your mouth and not through your nose. Do not block airflow with your tongue.

5. You can also wash all parts of the nebulizer in a dishwasher (except tubing). Place the nebulizer parts in a dishwasher basket, then place on the top rack of the dishwasher. Remove and dry the parts when the cycle is complete.

6. Follow the manufacturer’s instructions for care and use of your compressor.

Filter Change:
1. DeVilbiss® Compressor filters should be changed every six months or sooner if filter turns completely gray in color.

Compressor Cleaning:
1. With power switch in the “Off” position, unplug power cord from wall outlet.

2. If there is no mist, check all tubing connections and confirm that the compressor is working properly.

3. Rinse thoroughly with warm water and shake out water.

4. Air dry or hand dry nebulizer parts on a clean, lint-free cloth. Reassemble nebulizer when dry, and store.

5. You can also wash all parts of the nebulizer in a dishwasher (except tubing). Place the nebulizer parts in a dishwasher basket, then place on the top rack of the dishwasher. Remove and dry the parts when the cycle is complete.

Disinfecting Your Nebulizer
Your nebulizer is for your use only — Do not share your nebulizer with other people. You must regularly disinfect the nebulizer. Failure to do so could lead to serious or fatal illness. Clean the nebulizer as described above. Every other treatment day, disinfect the nebulizer parts (except tubing) by boiling them in water for a full 10 minutes. Dry parts on a clean, lint-free cloth.

Care and Use of Your Pulmo-Aide® Compressor

To reduce the risk of infection, illness or injury from contamination, you must thoroughly clean all parts of the nebulizer as instructed after each treatment. Never use a nebulizer with a clogged nozzle. If the nozzle is clogged, no aerosol mist is produced which will alter the effectiveness of the treatment. Replace the nebulizer if clogging occurs.

1. Remove tubing from nebulizer and disassemble nebulizer parts.

2. Wash all parts (except tubing) with warm water and liquid dish soap.

3. Rinse thoroughly with warm water and shake out water.

4. Air dry or hand dry nebulizer parts on a clean, lint-free cloth. Reassemble nebulizer when dry, and store.

5. You can also wash all parts of the nebulizer in a dishwasher (except tubing). Place the nebulizer parts in a dishwasher basket, then place on the top rack of the dishwasher. Remove and dry the parts when the cycle is complete.

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1. Remove tubing from nebulizer and disassemble nebulizer parts.

2. Wash all parts (except tubing) with warm water and liquid dish soap.

3. Rinse thoroughly with warm water and shake out water.

4. Air dry or hand dry nebulizer parts on a clean, lint-free cloth. Reassemble nebulizer when dry, and store.

Follow the manufacturer’s instructions for care and use of your compressor.

Filter Change:
1. DeVilbiss® Compressor filters should be changed every six months or sooner if filter turns completely gray in color.

Compressor Cleaning:
1. With power switch in the “Off” position, unplug power cord from wall outlet.

2. Wipe outside of the compressor cabinet with a clean, damp cloth every few days to keep dust free.

Caution: Do not submerge in water; doing so will result in compressor damage.

Storage Instructions
You should store tobramycin inhalation solution ampules in a refrigerator (2°C to 8°C or 36°F to 46°F). However, when you don’t have a refrigerator available (e.g., transporting your tobramycin inhalation solution), you may store the foil pouches (opened or unopened) at room temperature (up to 25°C/77°F) for up to 28 days.

Avoid exposing tobramycin inhalation solution ampules to intense light.

Unrefrigerated tobramycin inhalation solution, which is normally slightly yellow, may darken with age; however, the color change does not indicate any change in the quality of the product. You should not use tobramycin inhalation solution if it is cloudy, if there are particles in the solution, or if it has been stored at room temperature for more than 28 days. You should not use tobramycin inhalation solution beyond the expiration date stamped on the ampule.

Additional Information
Nebulizer: 1-800-327-8632
Compressor: 1-800-338-1988
Tobramycin Inhalation Solution: 1-877-835-5472
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