

Instructions for Use
PULMOZYME® (PULL-muh-zyme)
(dornase alfa)
Inhalation Solution

Instructions for Use with Jet Nebulizers and Compressors

See the other side of this Instructions for Use for information on use of Pulmozyme with the ultrasonic eRapid™ Nebulizer System

Read this Instructions for Use before you start taking Pulmozyme and each time you get a refill. There may be new information. This information does not take the place of talking to your doctor about your medical condition or your treatment.

A nebulizer and a compressor are used together to give a dose of Pulmozyme. A nebulizer changes the Pulmozyme liquid medicine into a fine mist you inhale by breathing through a mouthpiece. A compressor gives the nebulizer power and makes the nebulizer work.

Pulmozyme should only be used with the approved nebulizers and compressors **listed below, or with the eRapid Nebulizer System (see other side).**

Do not use any other inhaled medicines in the nebulizer at the same time. Keep all other inhaled medication systems completely separate from Pulmozyme.

Do not use a mask. Use the mouthpiece provided with each nebulizer kit.

If your child cannot breathe in or breathe out by mouth, you may use the PARI BABY™ reusable nebulizer, but you should discuss it with your doctor first. The PARI BABY™ nebulizer is the same as the PARI LC Plus Jet system, except the mouthpiece is replaced by a tight fitting face mask connected to an elbow piece.

Follow the steps on this side of the sheet to administer Pulmozyme using the following jet nebulizer systems.

| Nebulizer | Compressor |
|----------------------------|-------------------|
| Hudson T Up-draft II® with | Pulmo-Aide® |
| Marquest Acorn II® with | Pulmo-Aide® |
| PARI LC® Plus with | PARI PRONEB® |
| PARI BABY™ with | PARI PRONEB® |
| Durable Sidestream® with | MOBILAIRE™ |
| Durable Sidestream® with | Porta-Neb® |

Supplies you will need to give a dose of Pulmozyme (See Figure A):

- **1** ampule of Pulmozyme
- Compressor
- Nebulizer cup and screw-on or snap-on cap
- Plastic T connector (not needed for Sidestream nebulizer or PARI BABY)
- Flexible aerosol tube (not needed for Sidestream nebulizer or PARI BABY)
- Clean mouthpiece or PARI BABY facemask
- Long connecting tube
- Nose clip (optional, not needed for PARI BABY)

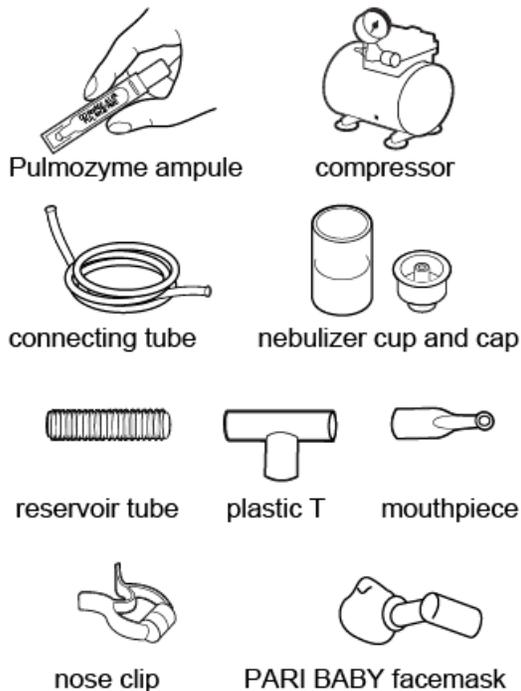


Figure A

Preparing the jet nebulizer and compressor:

Step 1. Clean a flat table surface and wash your hands.

- Clean a flat table surface.
- Wash your hands well with soap and water before using the Pulmozyme ampule and nebulizer. This helps prevent infection (**See Figure B**).



Figure B

Step 2. Gather the nebulizer and test the compressor.

- Place the nebulizer parts on a clean, flat table surface within reach.
- Test the compressor by turning it on and putting your finger in front of the "air out" or "air" port to feel air flowing. Turn off the compressor (**See Figure C**).
- For the MOBILAIRE™ compressor only, turn the pressure control knob fully to the right for the highest pressure output.



Figure C

Step 3. Gather the Pulmozyme ampule and check the expiration date.

- Remove **1** foil pouch of Pulmozyme from the refrigerator. Open the foil pouch and remove **1** ampule of Pulmozyme. Put the remaining ampules back in the foil pouch and return them to the refrigerator.
- Check the expiration date printed on the ampule (**See Figure D**).
Do not use the Pulmozyme ampule if the expiration date has passed.



Figure D

Step 4. Check the Pulmozyme ampule.

- Check the ampule for leaks by turning it upside down and gently squeezing (**See Figure E**). **Do not** use the ampule if it is leaking. Throw it away and get a new one.
- Check the Pulmozyme liquid in the ampule and make sure it is clear and free of particles. **Do not** use Pulmozyme if the liquid is cloudy or discolored. Take the Pulmozyme back to the pharmacy, hospital, or clinic that gave you the medicine.



Figure E

Step 5. Attach the tube to the compressor.

- Attach the long connecting tube to the "air out" or "air" port on the compressor (**See Figure F**).

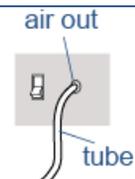


Figure F

Step 6. Attach the mouthpiece.

- **Skip to Step 7 if you use the Sidestream nebulizer or the PARI BABY nebulizer.**
- Push the mouthpiece into the wider end of the plastic T. Attach the flex tube to the other end of the T (**See Figure G**).

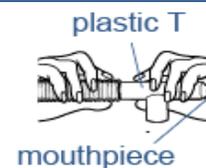


Figure G

Step 7. Remove the cap from the cup.

- Unscrew or unsnap the cap from the nebulizer cup (**See Figure H**).



Figure H

- Put the nebulizer cup on the table face up and place the cap upside down on a clean surface (**See Figure I**).



Figure I

Step 8. Open the Pulmozyme ampule.

- Hold the tab at the bottom of the Pulmozyme ampule firmly. Twist off the top. **Do not** squeeze the body of the ampule (**See Figure J**).



Figure J

Step 9. Pour the full Pulmozyme dose into the nebulizer.

- Turn the ampule upside down and squeeze gently to empty the medicine into the nebulizer cup. Keep squeezing until the ampule is empty. It is very important you squeeze all of the medicine out of the ampule (**See Figure K**).
- Screw or snap the cap onto the nebulizer cup (**See Figure L**).



Figure K



Figure L

Step 10. Connect the plastic T.

- Connect the plastic T to the nebulizer cap (**See Figure M**).



Figure M

- **If you are using the Sidestream nebulizer, attach the mouthpiece to the top of the nebulizer (See Figure N).**



Figure N

- **If you are using the PARI BABY nebulizer, connect the elbow piece and mask to the nebulizer outlet (See Figure O).**



Figure O

Step 11. Attach the tube to the cup.

- Connect the open end of the long tube to the port on the bottom of the nebulizer cup by pushing up firmly (**See Figure P**).

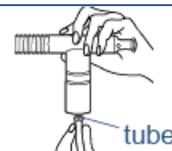


Figure P

Step 12. Turn on the compressor.

- Turn on the compressor and check to see that mist is coming out of the nebulizer (**See Figure Q**).
- **If you are using the MOBILAIRE™ compressor, turn the compressor control knob fully to the right, then turn on the compressor. The pressure gauge should move between 35 psi and 45 psi, the highest pressure output (See Figure R).**



Figure Q



Figure R

Taking your dose of Pulmozyme with a nebulizer:

Step 13. Breathe through the mouthpiece.

- **Skip to Step 14 if you are using the PARI BABY to give Pulmozyme to your child.**
- Place the mouthpiece between your teeth and on top of your tongue (**See Figure S**).
- Breathe slowly in and out through your mouth. Do not block the airflow with your tongue.
- Do not breathe through your nose. If you have problems breathing only through your mouth, use a nose clip (**See Figure T**).
- Do not be concerned if liquid droplets form in the long connecting tube during treatment. When the nebulizer begins spitting, gently tap the nebulizer cup and continue breathing until the nebulizer cup is empty or stops making mist (**See Figure U**).
- If you need to stop treatment before you are finished, or you begin coughing, turn off the compressor and do not spill any of the medicine.
- To start treatment again, turn on the compressor and continue breathing slowly in and out through your mouth.
- The complete treatment usually takes from **10 to 15** minutes for most nebulizers and compressors.
- If you are using the Sidestream nebulizer with the MOBILAIRE™ or Porta-Neb compressors, treatment usually takes from **2 to 6** minutes.
- It is important to inhale the full dose of Pulmozyme. If you find a leak or feel any moisture coming from the nebulizer during treatment, turn off the compressor and check to make sure the nebulizer cap is sealed correctly before continuing (**See Figure V**).



Figure S



Figure T



Figure U



Figure V

If you are using the PARI BABY nebulizer to give Pulmozyme to your child, follow the instructions below in Step 14. If not, go to Step 15

Step 14. Breathing through the facemask

- During the treatment your child may sit, lie down or stand.
- Place the facemask gently but firmly over your child's nose and mouth (**See Figure W**).
- **Make sure there are no air gaps between the mask and your child's face. This will help make sure that your child will get the full dose of Pulmozyme.**
- It is important that you try to keep the body of the nebulizer upright during the entire treatment (**See Figure W**). The elbow piece will allow you to move the mask for a good fit while keeping the nebulizer body upright.
- When the nebulizer begins "spitting," gently tap the nebulizer cup and continue treatment until the nebulizer is empty or stops making a mist (**See Figure X**).
- **If you need to stop the treatment or your child begins to cough during treatment, turn the compressor off. Do not spill any Pulmozyme.**
- If you have not removed the mask and you want to begin the treatment again, turn on the compressor.
- If you have removed the mask, repeat the steps above to replace the mask on your child's face and restart the compressor.
- The complete treatment usually takes from **10 to 15** minutes.



Figure W

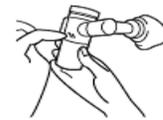


Figure X

It is important that your child inhale the full dose of Pulmozyme. If you find a leak or feel moisture coming from the nebulizer during the treatment, turn off the compressor and make sure the nebulizer cap is sealed correctly before starting the compressor again (**See Figure Y**).



Figure Y

After your treatment with Pulmozyme:

Step 15. Prepare the nebulizer for cleaning and storage.

- Turn off the compressor and take apart the nebulizer system. Set aside the flex tube and the long connecting tube.

Note: The Sidestream nebulizer does not use a flex tube.

- Throw away the Pulmozyme ampule in your household trash.
- Follow the manufacturer's recommendations for care of your nebulizer and compressor.

How should I store Pulmozyme?

- Store Pulmozyme in its foil pouch in the refrigerator between 36°F to 46°F (2°C to 8°C) until you are ready to use it.
- When traveling, Pulmozyme should be kept cold in its foil pouch.
- **Do not** freeze Pulmozyme.
- Protect Pulmozyme from excessive heat and strong light.
- **Do not** use Pulmozyme if it has been left at room temperature for a total time of **24** hours or if it becomes cloudy or discolored.
- **Do not** use Pulmozyme past the expiration date printed on the ampule.

This Instructions for Use has been approved by the U.S. Food and Drug Administration.

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Instructions for Use
PULMOZYME® (PULL-muh-zyme)
(dornase alfa)
Inhalation Solution

Instructions for Use with the eRapid™ Nebulizer System

**See the other side of this Instructions for Use for information on use
with Jet Nebulizers and Compressors**

Read this Instructions for Use before you start taking Pulmozyme and each time you get a refill. There may be new information. This information does not take the place of talking to your healthcare provider about your medical condition or your treatment.

This information does not take the place of the Manufacturer's eRapid Nebulizer System Instruction Booklet. This information is needed to show you the right way to use the eRapid Nebulizer System.

The eRapid Nebulizer System changes the Pulmozyme liquid medicine into a fine mist you inhale by breathing through a mouthpiece.

Do not use any other inhaled medicines in the nebulizer at the same time. Keep all other inhaled medication systems completely separate from Pulmozyme.

The eRapid Nebulizer System should only be used by adults and children who can use a mouthpiece, and not by younger children who need a mask to take Pulmozyme.

Follow the instructions on this side of the sheet to give Pulmozyme using the eRapid Nebulizer System.

Supplies you will need to give a dose of Pulmozyme (See Figure A):

- **1** ampule of Pulmozyme
- eRapid Nebulizer System, including the:
 - eRapid Nebulizer Handset (handset)
 - eBase Controller (controller)
- Power source for the controller, using **either**:
 - **4** "AA" batteries (disposable or rechargeable)
 - or an AC Power Supply plugged into a typical wall outlet (110 volt power outlet)
- Nose clip (optional)
- Manufacturer's eRapid Nebulizer System Instruction Booklet

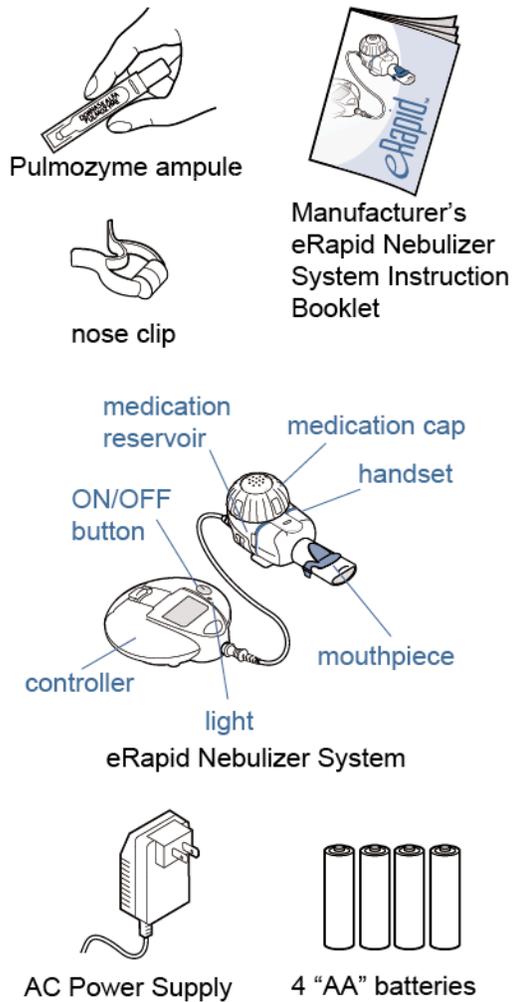


Figure A

Preparing the eRapid nebulizer system:

Step 1. Clean a flat table surface and wash your hands.

- Clean a flat table surface.
- Wash your hands well with soap and water before using the Pulmozyme ampule and nebulizer. This helps prevent infection (**See Figure B**).



Figure B

Step 2. Gather the nebulizer and test it.

- Place the eRapid system parts on a clean, flat table surface within reach.
- Make sure the controller batteries are charged **or** that the unit is plugged into a power outlet **(See Figure C)**.
- Press and hold the **ON/OFF** button on the controller for a few seconds to test if the controller will turn on **(See Figure D)**.
- When controller is turned on, press and hold the **ON/OFF** button to turn the controller off.

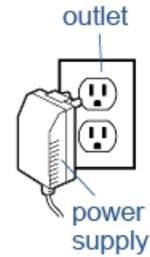


Figure C

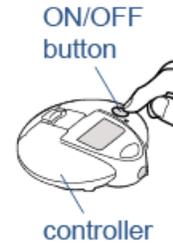


Figure D

Step 3. Gather the Pulmozyme ampule and check the expiration date.

- Remove **1** foil pouch of Pulmozyme from the refrigerator. Open the foil pouch and remove **1** ampule of Pulmozyme. Put the remaining ampules back in the foil pouch and return them to the refrigerator.
- Check the expiration date printed on the ampule **(See Figure E)**.
Do not use Pulmozyme ampule if expiration date has passed.



Figure E

Step 4. Check the Pulmozyme ampule.

- Check the ampule for leaks by turning it upside down and gently squeezing **(See Figure F)**.
Do not use the ampule if it is leaking. Throw it away and get a new one.
- Check the Pulmozyme liquid in the ampule and make sure it is clear and free of particles.
Do not use Pulmozyme if the liquid is cloudy or discolored. Take the Pulmozyme back to the pharmacy, hospital, or clinic that gave you the medicine.

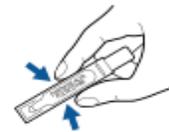


Figure F

Step 5. Put together the eRapid nebulizer system.

- The eRapid Nebulizer System has several small parts that must be put together the right way to give your dose of Pulmozyme (**Figure G**).
- The parts must be cleaned and disinfected at least **1** time before first use.
- See the **Manufacturer's eRapid Nebulizer System Instruction Booklet** for cleaning instructions and step-by-step instructions for how to put together your eRapid Nebulizer System (**See Figure G**).



Step 6. Open the Pulmozyme ampule.

- Hold the tab at the bottom of the Pulmozyme ampule firmly. Twist off the top. **Do not** squeeze the body of the ampule (**See Figure H**).



Figure H

Step 7. Pour the full Pulmozyme dose into the nebulizer.

- Turn the ampule upside-down and squeeze gently to empty the medicine into the medication reservoir. Keep squeezing until the ampule is empty. It is very important that you squeeze out all the medicine in the ampule (**See Figure I**).

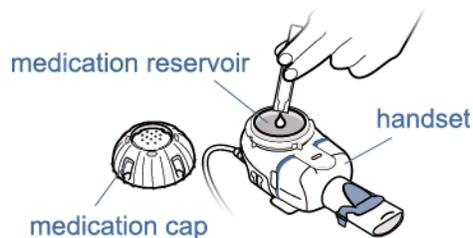


Figure I

Step 8. Place the cap on the Medication Reservoir.

- Line up the tabs on medication cap with the slots on medication reservoir (**See Figure J**).
- Turn medication cap clockwise until it stops (**See Figure J**).

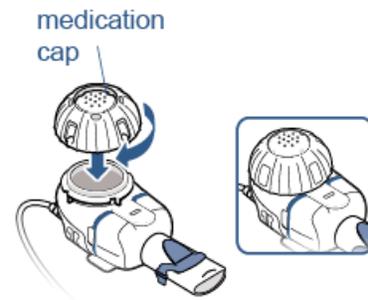


Figure J

Step 9. Turn on the nebulizer.

- Press and hold **ON/OFF** button on the controller for a few seconds (**See Figure K**).

ON/OFF
button



Figure K

- The controller will beep and the light will turn green. The nebulizer will start making mist (**See Figure L**).

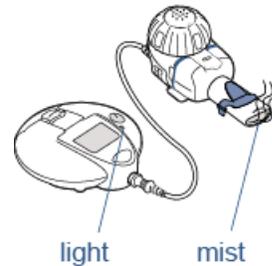


Figure L

Taking your dose of Pulmozyme:

Step 10. Breathe through the mouthpiece.

- Place the mouthpiece between your teeth and on top of your tongue (**See Figure M**).
- Breathe slowly in and out through your mouth. Do not block medicine flow with your tongue.
- Do not breathe through your nose. If you have problems breathing only through your mouth, use a nose clip (**See Figure N**).

mouth-
piece

Figure M

nose clip



Figure N

- If you need to stop treatment before you are finished, or you begin coughing, press and hold the **ON/OFF** button on the controller for **1** second (**See Figure O**).
- To restart your treatment, press and hold the **ON/OFF** button for **1** second.
- **Continue your treatment until the controller beeps twice.**
- The nebulizer will shut off by itself when your dose is complete. The complete treatment usually takes from **1 minute to 5** minutes.



Figure O

Step 11. Check that you received your full dose.

- After your treatment, about **1/5** teaspoon (**1mL**) of medicine should be left in the medication reservoir (**See Figure P**).
- Open the medication cap and check the medication reservoir. If more than **1/5** teaspoon (**1 mL**) is left in the medication reservoir, put the medication cap back on and continue treatment.
- When treatment is complete, **throw away** the **1/5** teaspoon (**1 mL**) of medicine that is left in the medication reservoir.



approx.
1/5 teaspoon
(1 mL)

Figure P

After Your Treatment with Pulmozyme:

Step 12. Cleaning the nebulizer

- If the controller is on, turn off the controller by pressing and holding the **ON/OFF** button.
- Take apart the nebulizer system.
- Throw away the empty Pulmozyme ampule in your household trash.
- See the **Manufacturer's eRapid Nebulizer System Instruction Booklet** for cleaning instructions (**See Figure Q**).
 - The handset, including the medication reservoir, medication cap, aerosol head, and mouthpiece, **must** be cleaned after each use and disinfected



Figure Q

after each day of use.

- Use of the EasyCare cleaning aid is recommended for cleaning the aerosol head located inside the handset **1** time each week.
- Replace the handset after you use your eRapid Nebulizer System **90** times. Replace it even if you use the EasyCare cleaning aid.
- Your handset has been tested for only **90** doses of Pulmozyme. Delivery of the right dose of PULMOZYME cannot be certain after **90** doses.

How should I store Pulmozyme?

- Store Pulmozyme in its foil pouch in the refrigerator between 36°F to 46°F (2°C to 8°C) until you are ready to use it.
- When traveling, Pulmozyme should be kept cold.
- **Do not** freeze Pulmozyme.
- Protect Pulmozyme from excessive heat and strong light.
- **Do not** use Pulmozyme if it has been left at room temperature for a total time of **24** hours or if it becomes cloudy or discolored.
- **Do not** use Pulmozyme past the expiration date printed on the ampule.

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