

INSTRUCTIONS FOR USE
PULMOZYME® (PULL-muh-zyme)
(dornase alfa)
Inhalation Solution

This Instructions for Use contains information on how to use PULMOZYME with Jet Nebulizers and Compressors

See the other side of this Instructions for Use for information on use of Pulmozyme with the recommended vibrating mesh nebulizers

Read and understand this Instructions for Use and the nebulizer manufacturer's instruction manual 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 appropriate compressors as **recommended below, or with the recommended vibrating mesh nebulizers (see other side of this Instructions for Use).** **Read and follow the manufacturer's instruction manual.**

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

Use the mouthpiece or face mask provided with the 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 Instructions for Use to give Pulmozyme using the following jet nebulizer systems

Jet Nebulizer	Compressor
Hudson T Up-draft II	A compressor with the following specifications is recommended: ■ Approximate air flow of 3.5 L/min to 12 L/min at approximately 20 psi to 45 psi pressure
Marquest Acorn II	
PARI LC Plus	
PARI BABY	
Durable Sidestream	

For additional information on an appropriate compressor to use with Pulmozyme, read the manufacturer's instruction manual for the recommended nebulizer.

Important Information You Need to Know Before Using PULMOZYME

Read and follow the nebulizer manufacturer's instruction manual for correct use and maintenance:

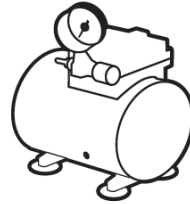
- to clean the nebulizer before first use and after each use as recommended.
- to disinfect the nebulizer parts by using the disinfecting method recommended.
- to replace nebulizer parts as recommended.

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

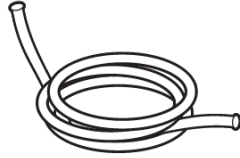
- 1 Pulmozyme ampule
- Compressor
- Nebulizer cup and cap (screw-on or snap-on)
- Plastic T (not needed for Sidestream nebulizer or PARI BABY)
- Flexible aerosol tube (not needed for Sidestream nebulizer or PARI BABY)
- Mouthpiece (clean) or PARI BABY facemask
- Long connecting tube
- Nose clip (optional,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



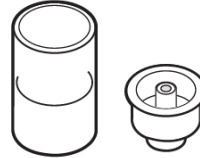
Pulmozyme ampule



compressor



long connecting
tube



nebulizer cup and cap



flexible aerosol
tube



plastic T



mouthpiece



nose clip



PARI BABY facemask

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)**.

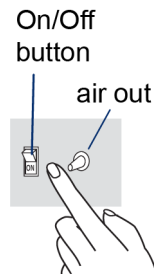


Figure C

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 (exp.) date printed on the ampule **(See Figure D)**.
- **Do not** use the Pulmozyme ampule if the expiration date has passed.

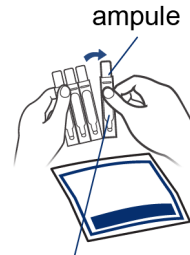


Figure D

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 long connecting tube to the compressor.

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

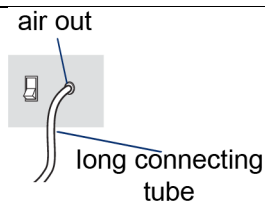


Figure F

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 flexible aerosol tube to the other end of the T (**See Figure G**).

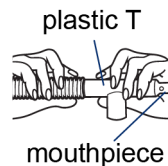


Figure G

Step 7. Remove the cap from the cup.

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

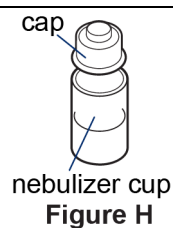


Figure H

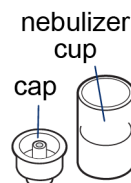


Figure I

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**).

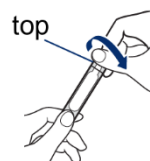


Figure J

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

- 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**).

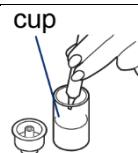


Figure K

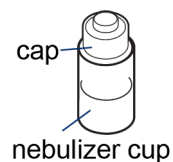


Figure L

Step 10. Connect the plastic T.

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

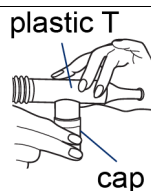


Figure M

- 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 long connecting tube to the cup.

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

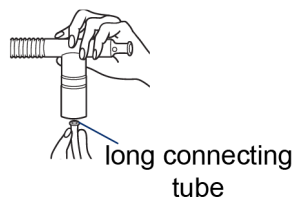


Figure P

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).



Figure Q

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 R).
- 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 S).

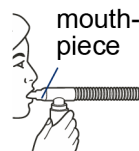


Figure R

- **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 T**).
- 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.
- If you are using the Sidestream nebulizer, 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 U**).

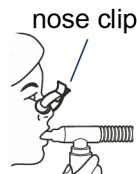


Figure S



Figure T

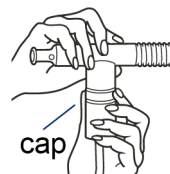


Figure U

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 V**).
- **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 V**). 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 W**).



Figure V

- **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.

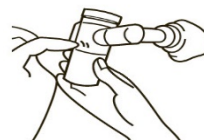


Figure W

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 X**).



Figure X

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 flexible aerosol tube and the long connecting tube.

Note: The Sidestream nebulizer does not use a flexible aerosol 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 ampules at a refrigerated temperature between 36°F to 46°F (2°C to 8°C) in their protective foil pouch to protect from light and heat** until you are ready to use them. When the protective foil pouch is opened, the unused ampules must be kept refrigerated in the protective foil pouch to protect from light and heat.
- When traveling, Pulmozyme ampules should be kept refrigerated in their protective foil pouch to protect from light and heat.
- Protect Pulmozyme from excessive heat and light.
- **Do not** use Pulmozyme if the ampules have been exposed to room temperature 72°F to 82°F (22°C to 28°C) for more than a total of **60** hours or if the solution has turned cloudy or discolored.
- **Do not** use Pulmozyme past the expiration date printed on the ampule.

Genentech, Inc.

A Member of the Roche Group

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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

This Instructions for Use contains information on how to use PULMOZYME with the following recommended vibrating mesh nebulizers:

Recommended Vibrating Mesh Nebulizers
eRapid® Nebulizer System
InnoSpire Go
Pulmogene Vibrating Mesh Nebulizer
AireHealth Nebulizer™
Intelligent Mesh Nebulizer

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

Read and understand this Instructions for Use and the nebulizer manufacturer's instruction manual 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 instruction manual for the vibrating mesh nebulizer.

The vibrating mesh nebulizer 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 Instructions for Use to give Pulmozyme using a vibrating mesh nebulizer.

Important Information You Need to Know Before Using PULMOZYME

Read and follow the nebulizer manufacturer's instruction manual for correct use and maintenance:

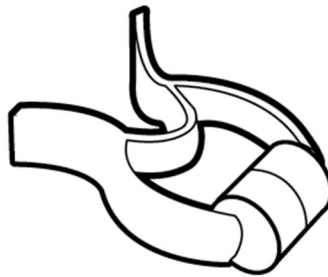
- to clean the nebulizer before first use and after each use as recommended
- to disinfect the nebulizer parts by using the disinfecting method recommended
- to replace nebulizer parts as recommended

Supplies you will need to give a dose of PULMOZYME:

- 1 Pulmozyme ampule **(See Figure A)**
- Vibrating mesh nebulizer and its parts
- Manufacturer's instruction manual for the vibrating mesh nebulizer
- **Nose clip (optional) (See Figure B)**



Pulmozyme ampule
Figure A



Nose Clip
Figure B

Prepare the vibrating mesh nebulizer:

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 C**).



Figure C

Step 2. Gather the nebulizer. Make sure you have all parts and make sure they are clean and not damaged. Prepare and test it as recommended in the manufacturer's instruction manual.

- Place the vibrating mesh nebulizer on a clean, flat table surface within reach. Make sure you have followed the manufacturer's instruction manual to make sure that the nebulizer is charged and ready for use.
-

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 (exp.) date printed on the ampule (**See Figure D**).

Do not use the Pulmozyme ampule if the expiration date has passed.

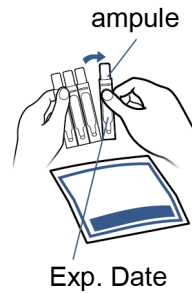


Figure D

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. Put the vibrating mesh nebulizer together.

- Put the nebulizer together according to the step-by-step manufacturer's **instruction manual**.

Step 6. Prepare to take the Pulmozyme treatment.

- Follow the manufacturer's instruction manual on how to add the Pulmozyme medicine to the nebulizer.
- 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 F**).
- Turn the ampule upside down and squeeze gently to empty the medicine into the medicine cup. Keep squeezing until the ampule is empty. It is very important that you squeeze out all the medicine in the ampule.

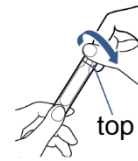


Figure F

Taking your dose of Pulmozyme with a nebulizer:

- Read the manufacturer's instruction manual on how to turn the nebulizer on and off and follow the steps for how to:
 - take your nebulized treatment,
 - breathe through the mouthpiece or facemask,
 - restart treatment if you need to stop before you are finished, and
 - confirm that your treatment is complete.

Step 7. Breathing through the mouthpiece.

- **Skip to Step 8 if you are using a facemask to take your dose of Pulmozyme.**
- Place the mouthpiece between your teeth and on top of your tongue.
 - Breathe slowly in and out through your mouth when using a mouthpiece. **Do not** block medicine flow with your tongue.
 - **Do not** breathe through your nose when using a mouthpiece. If you have problems breathing only through your mouth, use a nose clip (**See Figure B**).

Step 8. Breathing through the facemask.

- Place the facemask gently but firmly over the nose and mouth.
- Make sure there are no air gaps between the mask and the face. This will help make sure that you will get the full dose of Pulmozyme.

After Your Treatment with Pulmozyme:

Step 9. Clean the nebulizer

- Throw away the empty Pulmozyme ampule in your household trash.
- Clean the nebulizer thoroughly after each use. Follow the **manufacturer's instruction manual** for cleaning the nebulizer.
- All nebulizer parts **must** be cleaned after each use and disinfected after each day of use as recommended in the manufacturer's instruction manual.
- Replace the handset as recommended in the manufacturer's instruction manual.

How should I store Pulmozyme?

- **Store Pulmozyme ampules at a refrigerated temperature between 36°F to 46°F (2°C to 8°C) in their protective foil pouch to protect from light and heat** until you are ready to use them. When the protective foil pouch is opened, the unused ampules must be kept refrigerated in the protective foil pouch to protect from light and heat.
- When traveling, Pulmozyme ampules should be kept refrigerated in their protective foil pouch to protect from light and heat.
- Protect Pulmozyme from excessive heat and light.
- **Do not** use Pulmozyme if the ampules have been exposed to room temperature at 72°F to 82°F (22°C to 28°C) for more than a total of **60** hours or if the solution has turned cloudy or discolored.
- **Do not** use Pulmozyme past the expiration date printed on the ampule.

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