

PRODUCT MONOGRAPH

PrPULMOZYME®

(dornase alfa)
recombinant

For inhalation, 1 mg/mL, 2.5 mg/ampoule

Professed Standard

An enzyme that cleaves DNA
(Mucolytic)

Distributed by:
Hoffmann-La Roche Limited
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Manufactured by:
Genentech Inc., USA

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P^rPULMOZYME[®]
dornase alfa

This leaflet is part III of a three-part "Product Monograph" published when PULMOZYME was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about PULMOZYME. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION**What the medication is used for:**

PULMOZYME is used to treat patients with cystic fibrosis. It helps to break down the thick mucous in the airways, which improves lung function and reduces the risk of respiratory tract infections.

What it does:

PULMOZYME contains the active ingredient dornase alfa (also called recombinant human deoxyribonuclease I or rhDNase) which is a man-made protein similar to a natural protein in your body called DNase. PULMOZYME works by helping to break down the thick mucous produced in the lungs of patients with cystic fibrosis.

When it should not be used:

If you are allergic to PULMOZYME or any of the ingredients it contains.

What the medicinal ingredient is:

dornase alfa

What the non-medicinal ingredients are:

calcium chloride, sodium chloride and water

What dosage forms it comes in:

Ampoule 2.5 mg

WARNINGS AND PRECAUTIONS**BEFORE using PULMOZYME talk to your doctor or pharmacist if:**

- you are allergic to other medicines, including those not prescribed by your doctor
- you are taking any other medicines, including those not prescribed by your doctor
- you are pregnant, plan to become pregnant, or are breastfeeding

This information will help your doctor and you decide whether you should use PULMOZYME and what extra care may need to be taken while you are on the medicine.

INTERACTIONS WITH THIS MEDICATION

You should continue to take your standard cystic fibrosis treatment while you are on PULMOZYME (for example, antibiotics, bronchodilators, enzyme supplements, vitamins, corticosteroids and pain killers).

PROPER USE OF THIS MEDICATION**Usual dose:**

The usual dose is the contents of one ampoule to be inhaled each day. Some patients may benefit from taking PULMOZYME twice a day. Your doctor will decide the best dose for you.

DO NOT INHALE PULMOZYME UNTIL YOUR DOCTOR HAS THOROUGHLY TRAINED YOU IN THE PROPER TECHNIQUE.

PULMOZYME should be administered only using the nebulizers and compressors listed in the following tables:

Recommended Jet Nebulizer and Compressor Systems

Jet Nebulizer	Compressor
Hudson T Up-draft II with	Pulmo-Aide
Marquest Acorn II with	Pulmo-Aide
PARI LC Plus Reusable Nebulizer with	PARI PRONEB
PARI BABY with	PARI PRONEB

Recommended Nebulizer System

eRapid Nebulizer System (Consisting of the eRapid Nebulizer Handset with eBase Controller)

Keep all other inhaled medication systems completely separate from PULMOZYME. Do not use any other inhaled medications in the nebulizer at the same time. Do not use a mask. Use the mouthpiece provided with each nebulizer kit.

If you are unable to breathe through your mouth for the entire nebulization period, you may use the reusable PARI BABY nebulizer. It is recommended that patients under 5 years of age use the PARI BABY nebulizer. Please talk to your doctor about using the PARI BABY nebulizer before you do this. The PARI BABY nebulizer is identical to the PARI LC Plus Reusable Nebulizer except that the mouthpiece is replaced by a tight-fitting facemask connected to an elbow piece.

The eRapid Nebulizer System directions for assembly and use are different from the other Jet Nebulizer and Compressor systems.

- If you are using **Jet Nebulizer and Compressor systems**, refer to **Section A**.
- If you are using the **eRapid Nebulizer System**, refer to **Section B**.

This information does not take the place of talking to your doctor about your medical condition or your treatment. In addition, this information does not take the place of the Manufacturer’s Instruction Booklet which is necessary for proper use of each device.

SECTION A) - JET NEBULIZER AND COMPRESSOR SYSTEMS

- Hudson T Up-draft II with Pulmo-Aide,
- Marquest Acorn II with Pulmo-Aide,
- PARI LC Plus Reusable Nebulizer with PARI PRONEB and
- PARI BABY with PARI PRONEB

IF YOU ARE USING THE eRAPID NEBULIZER SYSTEM, REFER TO SECTION B.

Items needed for administration

- 1 ampoule of PULMOZYME
- Compressor
- Nebulizer cup and screw-on or snap-on cap
- Plastic T connector (not needed for PARI BABY)
- Flexible aerosol tube (not needed for PARI BABY)
- Clean mouthpiece or PARI BABY facemask
- Long connecting tube
- Nose clip (optional, not needed for PARI BABY)
- Manufacturer’s Nebulizer System Instruction Booklet

THE FOLLOWING INSTRUCTIONS ARE A GUIDE FOR ASSEMBLY AND USE OF THE RECOMMENDED NEBULIZER SYSTEMS :

Preparing the Treatment

1. Wash your hands thoroughly with soap and water before preparing the medication. This helps prevent infection.
2. Clean a table surface and lay out the nebulizer components. Place the compressor on the table within reach. Test the compressor by turning it on and putting your finger in front of the “air out” port to feel air flowing. Turn off the compressor.
3. Remove one ampoule of PULMOZYME from its pouch stored in the refrigerator and make sure the expiration date has not passed. Do not use PULMOZYME ampoule if expiration date has passed. Test the ampoule for leaks by turning it upside down and gently squeezing. If there appears to be a leak, do not use that ampoule of PULMOZYME. Next, check the PULMOZYME solution. It should be clear and free of particles. Do not use the PULMOZYME solution if it is cloudy or discoloured, but return it to your doctor or pharmacist.
4. Attach the long connecting tube to the “air out” port on the compressor.
5. Push the mouthpiece into the wider end of the plastic T. Attach the flex tube to the other end of the T. (For the PARI BABY, skip this step.)
6. Unscrew or unsnap the cap from the nebulizer cup. Put the cup on the table face up.
7. Hold the tab at the base of the ampoule of PULMOZYME firmly, taking care not to squeeze the body of the ampoule, and twist off the top.
8. Turn the ampoule upside-down and squeeze gently to empty contents into the nebulizer cup. Continue squeezing until the ampoule is empty. **It is very important that you use the full dose of the drug.** Screw or snap the cap onto the nebulizer cup.
9. Connect the plastic T to the nebulizer cap. (For the PARI BABY, connect the elbow piece and mask to the nebulizer outlet.)
10. Connect the open end of the long tube to the port on the bottom of the nebulizer cup by pushing up firmly.
11. Turn on the compressor and check to see that mist is coming out of the nebulizer.

Taking the Treatment

IF YOU ARE USING A NEBULIZER OTHER THAN PARI BABY USE THE FOLLOWING INSTRUCTIONS:

1. Place the mouthpiece between your teeth and on top of your tongue. Be sure that you do not block the airflow with your tongue. Breathe normally by inhaling and exhaling through your mouth. **Do not breathe through your nose.** If you have difficulty breathing only through your mouth, use a nose clip.
2. Do not be concerned if condensation collects 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 producing mist.

If you are interrupted or begin coughing during treatment, turn off the compressor taking care not to spill any of the drug. To resume treatment, turn on the compressor and continue. The complete treatment usually takes from 10 to 15 minutes.

It is important to inhale the full dose of PULMOZYME. If you detect a leak or feel any moisture coming from the nebulizer during treatment, turn off the compressor and check to be sure the nebulizer cap is sealed correctly before continuing.

IF YOU ARE USING THE PARI BABY NEBULIZER TO GIVE PULMOZYME TO YOUR CHILD YOU SHOULD USE THE FOLLOWING INSTRUCTIONS:

1. Place the facemask gently but firmly over the nose and mouth of your child. Make sure there are no air gaps between the mask and your child’s face. This will help ensure that your child will get the full dose of PULMOZYME. During the treatment your child may sit, lie down or stand. It is important that you try to keep the body of the nebulizer upright during the entire treatment period. The elbow piece will allow you to adjust the position of the mask while keeping the nebulizer body upright.

2. When the nebulizer begins “spitting”, gently tap the nebulizer cup and continue treatment until the nebulizer is empty or stops producing a mist.
 - If you are interrupted or your child begins to cough during treatment, turn the compressor off, taking care not to spill any PULMOZYME.
 - If you have not removed the mask and you wish to begin treatment again, simply turn on the compressor.
 - If you have removed the mask repeat Step 1. A complete treatment usually takes about 10 to 15 minutes.
3. It is important that you child inhale the full dose of PULMOZYME. If you detect a leak or feel moisture coming from the nebulizer during treatment, turn off the compressor and make sure the nebulizer cap is sealed correctly before starting the compressor again.

After the Treatment

Turn off the compressor and disassemble the nebulizer system, setting aside the flex tube and the long connecting tube.

FOLLOW MANUFACTURER’S RECOMMENDATIONS FOR CARE OF YOUR NEBULIZER AND COMPRESSOR.

SECTION B) - eRAPID NEBULIZER SYSTEM

- eRapid Nebulizer consisting of the eRapid Nebulizer Handset with eBase Controller

IF YOU ARE USING JET NEBULIZER AND COMPRESSOR SYSTEMS, REFER TO SECTION A.

Items needed for administration

- 1 ampoule of PULMOZYME
- eRapid Nebulizer System, consisting of:
 - eRapid Nebulizer Handset (handset)
 - eBase Controller (controller)
- Power source consisting of:
 - Controller can be used with 4 “AA” batteries (disposable or rechargeable)
 - Controller can also be used with AC Power Supply plugged into a typical wall outlet (110 volt power outlet)
- Nose clip (optional)
- Manufacturer’s eRapid Nebulizer System Instruction Booklet

THE FOLLOWING INSTRUCTIONS ARE A GUIDE FOR ASSEMBLY AND USE OF THE eRapid NEBULIZER SYSTEM:

Preparing the Treatment

1. Wash your hands thoroughly with soap and water before preparing the medication. This helps prevent infection.
2. Clean a table surface and lay out the nebulizer components. Make sure the controller batteries are charged or that the unit is plugged into a power outlet. Press and hold the ON/OFF button on the controller for a few seconds to test if the controller will turn on. When controller is turned on, press and hold the ON/OFF button to turn the controller off.
3. Remove one ampoule of PULMOZYME from its pouch stored in the refrigerator and make sure the expiration date has not passed. Do not use PULMOZYME ampule if expiration date has passed. Test the ampoule for leaks by turning it upside down and gently squeezing. If there appears to be a leak, do not use that ampoule of PULMOZYME. Next, check the PULMOZYME solution. It should be clear and free of particles. Do not use the PULMOZYME solution if it is cloudy or discoloured, but return it to your doctor or pharmacist.
4. To assemble the eRapid Nebulizer System, follow the Manufacturer’s eRapid Nebulizer System Instruction Booklet for cleaning instructions and step-by-step assembly instructions, such as: Components must be cleaned and disinfected at least once before first use. The eRapid Nebulizer System has several small parts that must be put together the right way to give your dose of PULMOZYME.
5. After you put together the eRapid Nebulizer System, prepare the PULMOZYME ampule. Hold the tab at the base of the ampoule of PULMOZYME firmly, taking care not to squeeze the body of the ampoule, and twist off the top.

- Turn the ampoule upside-down and squeeze gently to empty contents into the medicine reservoir. Continue squeezing until the ampoule is empty. **It is very important that you use the full dose of the drug.** Line up the tabs on medicine cap with the slots on medicine reservoir. Turn medicine cap clockwise until it stops and the nebulizer handset is now almost ready for use.
- Press and hold ON/OFF button on the controller for a few seconds. The controller will beep and the light will turn green. The nebulizer will start making mist.

Taking the Treatment

- Keep the eRapid Nebulizer handset level when in use. If the handset is tilted, the dosage may not be accurate.
- Place the mouthpiece between your teeth and on top of your tongue. Be sure that you do not block the airflow with your tongue. Breathe normally by inhaling and exhaling through your mouth. **Do not breathe through your nose.** If you have difficulty breathing only through your mouth, use a nose clip.
- If you are interrupted or begin coughing during treatment, turn off the nebulizer controller by pressing and holding the ON/OFF button on the controller for 1 second. To resume treatment, press and hold the ON/OFF button for 1 second and continue the 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 to 5 minutes.

After the Treatment

- It is important to inhale the full dose of PULMOZYME.** After your treatment, about 1/5 teaspoon (1 mL) of medicine should be left in the medicine reservoir. Open the medicine cap and check the medicine reservoir. If more than 1/5 teaspoon (1 mL) is left in the medicine reservoir, put the medicine 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 medicine reservoir.
- If the nebulizer 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. Specifically, when the eRapid Nebulizer is used for PULMOZYME medicine delivery, the use of the EasyCare cleaning aid is recommended for cleaning the aerosol head once a week. As per the EasyCare cleaning aid Instructions For Use, aerosol head should not be cleaned more than 25 times with the EasyCare cleaning aid.

FOLLOW MANUFACTURER'S RECOMMENDATIONS FOR CARE OF YOUR NEBULIZER SYSTEM.

Overdose:

If you take more than the prescribed amount of PULMOZYME, contact your doctor right away.

In case of drug overdose, contact a health care practitioner, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

Missed Dose:

If a dose of PULMOZYME is missed, take it as soon as possible. If it is almost time for the next dose, skip the missed dose and go back to the regular dosing schedule. Do not double doses.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

The most common side effects are voice alteration, sore throat, laryngitis, cough, rash, chest pain, and conjunctivitis. These effects are generally mild and they usually go away within a few weeks after starting therapy.

This is not a complete list of side effects. For any unexpected effects while taking PULMOZYME, contact your doctor or pharmacist.

HOW TO STORE IT

- Refrigerate in its foil pouch at 2-8°C.
- Store away from heat and direct light. Do not use the medicine if it has been exposed to room temperature for more than 24 hours.
- Do not use this medicine if it becomes cloudy or discoloured.
- Do not use this medicine after the expiry date on the package.
- Keep out of reach of young children.

REPORTING SUSPECTED SIDE EFFECTS

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

- **Report online at www.healthcanada.gc.ca/medeffect**
- **Call toll-free at 1-866-234-2345**
- **Complete a Canada Vigilance Reporting Form and:**
 - Fax toll-free to 1-866-678-6789, or
 - Mail to: **Canada Vigilance Program
Health Canada
Postal Locator 0701D
Ottawa, Ontario
K1A 0K9**

Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect™ Canada Web site at www.healthcanada.gc.ca/medeffect.

NOTE: Should you require information related to the management of side effects, contact your health professional. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

This document plus the full product monograph, prepared for health professionals can be found at:

www.rochecanada.com

or by contacting the sponsor, Hoffmann-La Roche Limited, at 1-888-762-4388.

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