

Package leaflet: Information for the user

Pulmozyme® 2500 U/2.5 ml Nebuliser Solution

dornase alfa

Please read all of this leaflet carefully before you start using this medicine because it contains important information for you.

Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist have told you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If any of the side effects become serious or troublesome, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist. See section 4.

What is in this leaflet

1. What Pulmozyme is and what it is used for
2. What you need to know before you use Pulmozyme
3. How to use Pulmozyme
4. Possible side effects
5. How to store Pulmozyme
6. Contents of the pack and other information

1. What Pulmozyme is and what it is used for

Pulmozyme contains a medicine called dornase alfa. It is a man-made version of a protein found in your body called 'DNase'. Pulmozyme is used for people with cystic fibrosis. It helps by breaking down the thick mucus found in lungs. This helps lungs of people with cystic fibrosis to work better. Pulmozyme is breathed in (inhaled) using something called a 'nebuliser' (see Section 3: How to use Pulmozyme). As well as using Pulmozyme you will normally keep taking the other medicines you use for cystic fibrosis (see 'Other medicines and Pulmozyme' in section 2).

2. What you need to know before you use Pulmozyme

Do not use Pulmozyme:

- if you are allergic (hypersensitive) to dornase alfa or any of the other ingredients in Pulmozyme (listed in section 6).

Warnings and precautions

Talk to your doctor or pharmacist before using Pulmozyme.

Children

Pulmozyme is not recommended for use by children under 5 years of age. Check with your doctor or pharmacist before using Pulmozyme if it has been prescribed for a child under 5 years of age.

Other medicines and Pulmozyme

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines. This includes medicines that you buy without a prescription and herbal medicines. This is because Pulmozyme may affect the way some medicines work. Also some other medicines may affect the way Pulmozyme works.

You can carry on using your usual treatments for cystic fibrosis when you are using Pulmozyme (such as antibiotics, pancreatic enzymes, bronchodilators and painkillers). If you are not sure about this, talk to your doctor or pharmacist before using Pulmozyme.

Pregnancy and breast-feeding

Do not use Pulmozyme if you are pregnant, trying to get pregnant or breast-feeding, unless your doctor has told you to.

Driving and using machines

Pulmozyme is not likely to affect you being able to drive or use any tools or machines.

3. How to use Pulmozyme

Always use Pulmozyme exactly as your doctor has told you. Pulmozyme is breathed in (inhaled) using a nebuliser (see 'Which nebuliser to use'). You should check with your doctor if you are not sure.

Keep having your standard chest physiotherapy when you are using Pulmozyme.

People 5 years of age and over

- You should use Pulmozyme **every day**.
- The recommended dose is one ampoule every day, inhaled using your nebuliser.

- If you are over 21, your doctor may tell you to use one ampoule twice a day.

People under 5 years of age

- Pulmozyme is not recommended in children under 5 years of age.

Which nebuliser to use:

Use a nebuliser such as:

- Hudson T Up-draft II/Pulmo-Aide, Airlife Misty/Pulmo-Aide, customised Respirgard/Pulmo-Aide, or AcornII/Pulmo-Aide.
- Pulmozyme may also be used with a reusable nebuliser system, such as the Pari LL/Inhalerboy, Pari LC/Inhalerboy or Master, Aiolos/2 Aiolos, Side Stream/CR50 or MobilAire or Porta-Neb.
- The Pari eFlow Rapid nebuliser, a general purpose electronic vibrating membrane nebuliser may be used. The Pari eFlow Rapid nebuliser should be cleaned according to manufacturer's instructions. In addition it is recommended to use the Pari EasyCare cleaning accessory after every seventh use.
- **Ultrasonic nebulisers must not be used**, as they may stop Pulmozyme from working properly.

Please read carefully and follow the manufacturers' instructions for use of each nebuliser.

Talk to your doctor as they will be able to tell you which nebulisers can be used with Pulmozyme.

How to use Pulmozyme with the nebuliser

When getting your nebuliser ready for use with Pulmozyme, **please remember these important points:**

- Do not mix Pulmozyme with any other liquids or medicines in the nebuliser.
- Do not use any left over Pulmozyme, this should always be thrown away.
- If you have a 're-usable' nebuliser, remember to clean it after use. The makers of the nebuliser will be able to give you the best advice on how to clean their equipment after using Pulmozyme.
- If someone else uses your Pulmozyme by mistake, they should talk to a doctor straight away.

To use your nebuliser

- Make sure that the nebuliser is clean.
- Snap the top off one Pulmozyme ampoule.
- Pour the contents into the nebuliser chamber.
- Follow the nebuliser instructions and inhale the Pulmozyme straight away.

If you use more Pulmozyme than you should

If you use more Pulmozyme than you should, talk to a doctor straight away.

If you forget to use Pulmozyme

- If you forget to take a dose, take it as soon as you remember.
- If it is nearly time for the next dose, skip the missed dose.
- Do not take a double dose to make up for a forgotten dose.

If you stop using Pulmozyme

If you stop using Pulmozyme your chest symptoms may get worse. Talk to your doctor if you would like to stop using Pulmozyme.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, Pulmozyme can cause side effects, although not everyone will get them.

Side effects from Pulmozyme are rare. They affect less than 1 in 1000 people.

Side effects include:

- Chest pain.
- Fever.
- Upset stomach (indigestion).
- Changes to your voice including hoarseness or loss of voice.
- Sore throat.
- Difficulty breathing.
- A runny or blocked nose and sneezing (rhinitis).
- Irritation of your eye (conjunctivitis). The signs include redness and itchiness of the eye and a discharge from the eye.
- Skin rash, which may be lumpy and itchy (hives).
- When you start your treatment, your lung function may get worse and you may produce more mucus than normal. This usually gets better with time.

If any of the side effects become serious or troublesome, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, Website: www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Pulmozyme

- Store in a refrigerator (2 °C to 8 °C). Keep the ampoule in the outer carton in order to protect from light.
- You can still use an ampoule if it has been left out of the refrigerator for only a short time at a higher temperature (only left out once and for no longer than 24 hours at temperatures up to 30 °C).
- Keep this medicine out of the sight and reach of children.
- Do not use this medicine after the expiry date which is stated on the pack after EXP. The expiry date refers to the last day of that month.
- Do not throw away any left over ampoules via wastewater or household waste. Instead, return them to your pharmacist so that they can be disposed of carefully. These measures will help protect the environment. Only keep them if your doctor tells you to.

6. Contents of the pack and other information

What Pulmozyme contains

- The active substance is dornase alfa. This is also known as recombinant human deoxyribonuclease 1 or rhDNase. Each 2.5 ml (millilitre) of liquid medicine contains 2500 Units (or 2.5 milligrams) of dornase alfa.
- The other ingredients are sodium chloride, calcium chloride dihydrate and water for injections

What Pulmozyme looks like and contents of the pack

Pulmozyme Nebuliser Solution is provided in clear plastic ampoules. The ampoules contain 2.5 ml of liquid medicine. The medicine is clear and colourless to slightly yellowish. Pulmozyme is supplied in cartons containing 6 ampoules.

Manufacturer

Roche Registration GmbH, Emil-Barell-Strasse 1, 79639 Grenzach-Wyhlen, Germany.

Product procured from within the EU, repackaged and distributed by the Parallel Product Authorisation holder:

PCO Manufacturing Ltd., Unit 10, Ashbourne Business Park, Rath, Ashbourne, Co. Meath, Ireland.

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Parallel Product Authorisation Number

PPA 465/433/1

This leaflet was last revised in February 2023.