

Pulmozyme®

Pronounced Pull-mo-zime

contains the active ingredient dornase alfa

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Pulmozyme inhalation solution.

It does not contain all the available information.

It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you using Pulmozyme against the benefits they expect it will have for you.

If you have any concerns about using this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What Pulmozyme is used for

Pulmozyme contains the active ingredient dornase alfa which is an enzyme.

Pulmozyme is used to help people who have cystic fibrosis (CF). CF is a hereditary disease in which secretions, mainly of the lung passages and pancreas, are affected. However, Pulmozyme is not a cure for this disease.

There are many different types of medicines used to treat CF.

The enzyme dornase alfa is almost identical to the one that is found in people without CF.

Enzymes are proteins that carry out normal processes in nature. Humans have hundreds of enzymes to help the body function properly.

The enzyme in Pulmozyme breaks down DNA contained in lung secretions (mucous). CF patients have too much of this substance.

Breaking down the excessive amounts of DNA reduces the thickness of the lung mucous.

As a result, Pulmozyme improves lung function and eases the symptoms of breathlessness, cough and congestion.

Pulmozyme also reduces the chance of lung infections and lowers the rate at which the disease affects the lungs. This decreases the need for injected (intravenous) antibiotics.

Your doctor, however, may have prescribed Pulmozyme for another purpose.

Ask your doctor if you have any questions about why Pulmozyme has been prescribed for you.

This medicine is available only with a doctor's prescription.

Pulmozyme is not addictive.

Before you use Pulmozyme

When you must not use it

Do not use Pulmozyme if:

- **you have had an allergic reaction to Pulmozyme or any ingredients listed at the end of this leaflet**
- **you have had an allergic reaction to protein of Chinese Hamster Ovary (CHO) origin**
- **the package is torn or shows signs of tampering**
- **the expiry date (EXP) printed on the pack has passed.**

If you use this medicine after the expiry date has passed, it may not work as well.

- **the solution in the ampoule is cloudy or discoloured.**

If you are not sure if you should be using Pulmozyme, talk to your doctor.

Before you start to use it

Tell your doctor if you:

- **are pregnant or plan to become pregnant.**

It is not known whether Pulmozyme is harmful to an unborn baby when used by a pregnant woman. If there is a need to use Pulmozyme when you are pregnant your doctor will discuss the risks and benefits to you and the unborn baby.

- **are breast-feeding or plan to breast-feed.**

It is not known whether Pulmozyme passes into the breast milk. Your doctor will discuss the risks and benefits of using Pulmozyme if you are breast-feeding

- **have any other health problems**
- **are allergic to any other medicines, foods, dyes or preservatives.**

If you have not told your doctor about any of the above, tell them before you start using Pulmozyme.

Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you have bought from a pharmacy, supermarket or health food shop.

Standard treatments for CF [antibiotics, bronchodilators, vitamins, inhaled and systemic (taken by mouth)]

corticosteroids] and pain killers can be used safely with Pulmozyme.

However, Pulmozyme should not be mixed in the nebuliser with these other treatments.

How to use Pulmozyme

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

How much to inhale

Use Pulmozyme exactly as your doctor has prescribed.

Your doctor will tell you when and how much Pulmozyme to inhale each day.

The usual dose for adults and children is the content of one ampoule inhaled once a day. For some people over 21 years of age, the dose may be increased to one ampoule twice a day.

How to use it

Pulmozyme should be inhaled using a nebuliser and compressor recommended below.

You must follow your doctor's instructions when using Pulmozyme with the nebuliser and compressor your doctor has recommended to you.

The manufacturer's instructions on the maintenance of the nebuliser and compressor should be followed. Instructions are usually available with the device.

Pulmozyme should not be diluted (watered down) or mixed with other medicines or solutions in the nebuliser bowl.

Recommended nebulisers and compressors

The following nebuliser/compressor combinations have been tested with Pulmozyme and found to be effective:

- Airlife Misty/Pulmo-Aide
- Hudson T Updraft II/Pulmo-Aide
- Customised Respiguard/ Pulmo-Aide
- Sidestream/Portaneb

The following nebuliser/compressor systems have been tested and are similar to those listed above:

- e-Flow Rapid nebuliser
- Pari LC Sprint/TurboBoy
- Rapid Flo/Ventalair
- Pari Baby Set/Pariboy Proneb
- Pari LC+/Pari Proneb

- Rapid Flo/Vitalair RapidNeb

There are some nebulisers that have not been tested with Pulmozyme and therefore may not be effective.

Ultrasonic nebulisers may be unsuitable for delivery of Pulmozyme as they may stop Pulmozyme from working properly.

How long to use Pulmozyme

Pulmozyme should be used long-term to help lung function and reduce the chance of lung infection.

Continue using Pulmozyme until your doctor tells you to stop.

If you forget to use Pulmozyme

Do not take an extra dose. Wait until the next dose and take your normal dose then.

Do not try to make up for the dose that you missed by taking more than one dose at a time.

In case of an overdose

Immediately telephone your doctor, or Poisons Information Centre (telephone 13 11 26), or go to Accident and Emergency at your nearest hospital, if you think you or anyone else may have inhaled too much Pulmozyme. Do this even if there are no signs of discomfort or poisoning.

Keep telephone numbers for these places handy.

If you are not sure what to do, contact your doctor or pharmacist.

While you are using Pulmozyme

Things you must do

Tell all doctors, dentists and pharmacists who are treating you that you are using Pulmozyme.

Throw out any left-over solution in the ampoule or nebuliser bowl. Pulmozyme cannot be kept for the next dose.

This is because Pulmozyme does not contain any preservatives.

Tell your doctor if you become pregnant while using Pulmozyme.

Tell your doctor if, for any reason, you have not used your medicine exactly as prescribed.

Otherwise, your doctor may think that it was not effective and change your treatment unnecessarily.

Tell your doctor if you feel Pulmozyme is not helping your condition.

Your doctor may adjust your dose or suggest alternative treatment.

Be sure to keep all of your appointments with your doctor so that your progress can be checked.

Things you must not do

Do not stop using Pulmozyme or change the dose without first checking with your doctor.

Do not let yourself run out of medicine over the weekend or on holidays.

Do not mix other medicines or solutions with Pulmozyme in the nebuliser bowl, unless advised to do so by your doctor.

Do not give Pulmozyme to anyone else even if they have the same condition as you.

Do not use Pulmozyme to treat other complaints unless your doctor says to.

Do not take any other medicines, whether they require a prescription or not, without first telling your doctor or consulting with a pharmacist.

Things to be careful of

Be careful driving or operating machinery until you know how Pulmozyme affects you.

Pulmozyme has not been shown to impair your ability to drive or operate machinery.

Side Effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are using Pulmozyme.

Pulmozyme helps most people with CF but it may have unwanted side effects in a few.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor if you notice any of the following and they worry you:

- voice hoarseness
- sore vocal cords
- sore throat
- skin rash
- chest pain
- conjunctivitis (sore, red, gritty or weeping eye/s).

This is not a complete list of all possible side effects. Others may occur in some people and there may be some side effects not yet known.

Tell your doctor if you notice anything else that is making you feel unwell, even if it is not in this list.

Ask your doctor or pharmacist if you do not understand anything in this list.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

After using Pulmozyme

Storage

Keep Pulmozyme ampoules in their protective foil pouches in their box in the fridge at 2 to 8°C until it is time to use them.

If you take the ampoules out of the pack they may not keep well.

Protect Pulmozyme from light.

Do not store Pulmozyme, or any other medicine, in a bathroom or near a sink.

Do not leave Pulmozyme in the car or on window sills.

Heat and dampness can destroy this medicine.

Keep Pulmozyme where young children cannot reach it.

Disposal

If your doctor tells you to stop using Pulmozyme, or the ampoules have passed their expiry date, ask your

pharmacist what to do with any ampoules that are left over.

Product Description

Availability

Pulmozyme comes in packs of 30 ampoules.

What Pulmozyme looks like

Pulmozyme is a clear, colourless to slightly yellow solution.

Ingredients

Active ingredient:

- Each ampoule contains 2.5 mg of dornase alfa.

Inactive ingredients:

- sodium chloride
- calcium chloride dihydrate
- water for injection.

Pulmozyme does not contain gluten, lactose, sucrose, tartrazine or any other azo dyes.

Distributor

Pulmozyme is distributed by:

Roche Products Pty Limited

ABN 70 000 132 865

Level 8, 30-34 Hickson Road

Sydney NSW 2000

AUSTRALIA

Medical enquiries: 1800 233 950

Please check with your pharmacist for the latest Consumer
Medicine Information.

Australian Registration Number:

AUST R 49822

This leaflet was prepared on 4 July 2018.