



Consumer Medicine Information

PULMOZYME[®]

Dornase alfa

2.5 mg/ 2.5 mL solution for inhalation

What is in this leaflet

This leaflet answers some common questions about PULMOZYME solution for inhalation.

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 expected for you.

If you have any concerns about taking 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 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.

PULMOZYME contains dornase alfa, which is an enzyme.

Enzymes are naturally occurring 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 a substance (DNA) contained in lung secretions (mucous). Cystic fibrosis patients have too much of this substance, and it is more viscous (thicker) than normal.

Breaking down the excessive amounts of DNA reduces the thickness of the lung mucous, making it easier to cough up and clear from the lungs.

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 slows down the progression of (but does not cure) the disease affecting the lungs. This decreases the need for injected (intravenous) antibiotics.

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

There is limited experience in the use of PULMOZYME in patients under the age of 5 years.

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

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

Before you use PULMOZYME

When you must not use it

Do not use PULMOZYME if:

- 1. you have had an allergic reaction to PULMOZYME or any ingredients listed at the end of this leaflet**
- 2. the package is torn or shows signs of tampering**
- 3. the expiry date printed on the pack has passed**
If you take this medicine after the expiry date has passed it may not work as well.
- 4. the solution in the ampoule is cloudy, discoloured or contains particles**

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:

- 1. you are pregnant or plan to become pregnant**
It is not known whether PULMOZYME is harmful to an unborn baby when taken by a pregnant woman. If there is a need to take PULMOZYME when you are pregnant your doctor will discuss the risks and benefits to you and the unborn baby.
- 2. you are breastfeeding or plan to breastfeed**
PULMOZYME is not expected to pass into breast milk. However, if there is a need to take PULMOZYME when you are breastfeeding your doctor will discuss the risks and benefits to you and the baby.
- 3. you have any other health problems**
- 4. you are allergic to any other medicines, foods, dyes or preservatives**

If you have not told your doctor about any of the above, do so before you start taking 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 cystic fibrosis (CF) such as antibiotics, bronchodilators (which widen the lung passages), pancreatic enzymes, vitamins, corticosteroids (taken by mouth or inhaled) and pain killers can be used safely with PULMOZYME.

However, PULMOZYME should not be mixed in the nebuliser with these, or any other medicines.

Your doctor or pharmacist has more information on medicines to be careful with or avoid while taking PULMOZYME.

Ask your doctor or pharmacist if you are not sure about any other medicines.

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 recommended dose for adults and children is the contents of one PULMOZYME 2.5 mg/ 2.5 mL 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 jet nebuliser (ultrasonic nebulisers are not suitable for PULMOZYME) with a compressor. Your doctor or nurse will advise you which nebulisers are suitable to use.

Ampoules are opened by twisting off the top of the plastic ampoule. The contents can then be squeezed into the nebuliser bowl.

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

After inhalation, 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.

You should continue your regular medical care, including chest physiotherapy, while taking PULMOZYME.

When to use it

PULMOZYME can be inhaled at any time of the day, but should be inhaled at around the same time each day.

How long to use it

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

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Otherwise, take it as soon as you remember and then go back to taking it as you would normally.

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

If you have trouble remembering your dose, ask your pharmacist for some hints.



In case of an overdose

Immediately telephone your doctor or National Poisons Information Centre (telephone 0800 POISON or 0800 764 766) for advice or go to your nearest Accident and Emergency Centre if you think that you or anyone else may have inhaled too much PULMOZYME, even if there are no signs of discomfort or poisoning.

You may need medical attention.

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.

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.

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.

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 other medicines whether they require a prescription or not without first telling your doctor or consulting a pharmacist.

Things to be careful of

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

However, PULMOZYME is not expected to affect your ability to drive a car or operate machinery.

Side effects

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



PULMOZYME helps most people with cystic fibrosis but it may have unwanted side effects. 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.

You may find when you start using PULMOZYME that your lung function may get worse and you may cough up more mucous than previously. This is a common effect of starting treatment and is usually temporary and can happen with any medicine administered as an aerosol (fine droplets in air).

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

- voice hoarseness, sore throat
- hayfever-like symptoms (runny and/or stuffy nose, sneezing)
- conjunctivitis (sore, red, gritty or weeping eyes)
- fever (high temperature)
- indigestion
- skin rash, itchiness or hives
- pain in the chest region
- breathlessness
- cough

These are the more common side effects of PULMOZYME. Mostly these are mild.

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 on 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

Cleaning

Ask your doctor or nurse about the proper use, maintenance and care of your nebuliser and compressor.

Storage

Keep PULMOZYME ampoules in their protective foil pouch in the outer carton in the fridge at 2°C – 8°C until it is time to use them.

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

However, a single brief exposure to room temperature (up to 30°C) for not more than 24 hours does not affect PULMOZYME.

Protect PULMOZYME from light.

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

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

Avoid exposure to excessive heat.



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 one strength – 2.5 mg/ 2.5 mL (1 mg/mL) dornase alfa solution.

PULMOZYME comes in packs of 6 single-use plastic ampoules wrapped in a foil pouch.

What PULMOZYME looks like

PULMOZYME is a clear, colourless to slightly yellowish solution.

Ingredients

Active ingredient - dornase alfa

Each ampoule contains 2.5 mg of dornase alfa in 2.5 mL of solution (1 mg/mL).

Inactive ingredients - sodium chloride, calcium chloride dihydrate, water for injection

Distributor

PULMOZYME is distributed by:

Roche Products (New Zealand) Limited
P O Box 12-492
Penrose
AUCKLAND 1642

Telephone: (09) 633 0700

Toll Free: 0800 656 464

This leaflet was prepared on 16 July 2008.

Reference: Pulmozyme Data Sheet dated 14 April 2008.