

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using Pulmozyme?

Pulmozyme contains the active ingredient dornase alfa. Pulmozyme is used to treat cystic fibrosis (CF), a hereditary disease that causes thick, sticky mucus to build up in the lungs and other parts of the body. It works by breaking down DNA in the mucus, improving lung function, easing symptoms, and reducing the risk of infections. Pulmozyme helps manage CF but is not a cure.

For more information, see Section [1. Why am I using Pulmozyme?](#) in the full CMI.

2. What should I know before I use Pulmozyme?

Do not use if you have ever had an allergic reaction to dornase alfa, have had a reaction to Chinese Hamster Ovary (CHO) proteins or any of the ingredients listed at the end of the CMI. Do not use if the package is damaged, expired or the solution is cloudy.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding. For more information, see Section [2. What should I know before I use Pulmozyme?](#) in the full CMI.

3. What if I am taking other medicines?

Tell your doctor or pharmacist about any medicines, vitamins, or supplements you are taking, including non-prescription products. Standard CF treatments like antibiotics, bronchodilators, vitamins, corticosteroids, and painkillers can be safely used with Pulmozyme, but they should not be mixed in the nebuliser.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use Pulmozyme?

- Inhale Pulmozyme using a nebuliser and compressor recommended by your doctor. Follow all device maintenance instructions. Pulmozyme should not be diluted (watered down) or mixed with other medicines in the nebuliser.
- Use Pulmozyme long-term unless instructed otherwise by your doctor.
- Take Pulmozyme at the same time each day. If you miss a dose, do not double up; take your next dose as scheduled.

More instructions can be found in Section [4. How do I use Pulmozyme?](#) in the full CMI.

5. What should I know while using Pulmozyme?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are using Pulmozyme.• Discard any leftover solution after each use; it cannot be reused.• Keep your doctor informed about your progress, missed doses, or if Pulmozyme seems ineffective.• Tell your doctor if you become pregnant or plan to become pregnant while using Pulmozyme.• Tell your doctor if you are breastfeeding or plan to breastfeed while using Pulmozyme.
Things you should not do	<ul style="list-style-type: none">• Do not stop using this medicine suddenly or change the dose without consulting your doctor.• Do not let yourself run out of Pulmozyme or use it to treat others even if they have the same condition as you.
Looking after your medicine	<ul style="list-style-type: none">• Store Pulmozyme in its foil pouches in the fridge (2–8°C) and protect it from light.• Avoid heat, moisture, and sunlight; do not store it in the bathroom, near a sink, or in the car.

For more information, see Section [5. What should I know while using Pulmozyme?](#) in the full CMI.

6. Are there any side effects?

Pulmozyme can cause side effects, but not everyone experiences them. Most are not serious, but some may require medical attention. Tell your doctor if you experience any of the following: voice hoarseness, sore vocal cords, sore throat, skin rash, chest pain, or conjunctivitis (red, sore, gritty, or weeping eyes). For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

PULMOZYME® (pronounced pull-mo-zime)

Active ingredient(s): dornase alfa

Consumer Medicine Information (CMI)

This leaflet provides important information about using Pulmozyme. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Pulmozyme.**

Where to find information in this leaflet:

1. [Why am I using Pulmozyme?](#)
2. [What should I know before I use Pulmozyme?](#)
3. [What if I am taking other medicines?](#)
4. [How do I use Pulmozyme?](#)
5. [What should I know while using Pulmozyme?](#)
6. [Are there any side effects?](#)
7. [Product details](#)

1. Why am I using Pulmozyme?

Pulmozyme contains the active ingredient dornase alfa which is an enzyme. Enzymes are proteins that carry out normal processes in the human body.

What it is used for

Pulmozyme is used to help people who have cystic fibrosis (CF).

- CF is a hereditary disease where the body produces abnormally thick and sticky secretions. This mainly affects the lung passages and the pancreas.
- Pulmozyme is only one part of the treatment for CF, and it is not a cure for this disease.

How Pulmozyme works

The enzyme in Pulmozyme, dornase alfa is almost identical to the one that is found in people without CF. Its job is to break down DNA that builds up in lung secretions (mucous). CF patients have too much of this substance.

- The DNA comes from dead white blood cells that accumulate in the airways.
- By breaking down this excessive DNA, Pulmozyme 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. If you are not sure if you should be using Pulmozyme, talk to your doctor.

2. What should I know before I use Pulmozyme?

Warnings

Do not use Pulmozyme if:

- you are allergic to dornase alfa, or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can use this medicine.
- 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.

Check with your doctor if you:

- have any other health problems
- are allergic to any other medicines, foods, dyes or preservatives.
- are younger than 5 years or if you are the caregiver of a child under 5 years. There is only limited experience using Pulmozyme in this age group.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend 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.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

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.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Standard treatments for CF [antibiotics, bronchodilators (medicines that expand the airways), 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.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Pulmozyme.

4. How do I use Pulmozyme?

How much to use

- 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 Pulmozyme

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. Continue using Pulmozyme until your doctor tells you to stop.

If you forget to use Pulmozyme

Always try to use Pulmozyme regularly at the same time each day. If you miss a dose, take your next dose at its scheduled time. **Do not take a double dose to make up for the dose you missed.**

If you use too much Pulmozyme

If you think that you have inhaled too much Pulmozyme, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using Pulmozyme?

Things you should 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, 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.

Call your doctor straight away if you:

- become pregnant while using Pulmozyme.

Things you should 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.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how Pulmozyme affects you.

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

Looking after your medicine

Follow the instructions in the carton on how to take care of your medicine properly.

- 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.
- Protect Pulmozyme from light.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Heat and dampness can destroy this medicine.

Keep it where young children cannot reach it.

When to discard your medicine

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.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

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

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
Mouth and throat <ul style="list-style-type: none">• hoarse or raspy voice• sore throat Skin and Allergy-Related Effects <ul style="list-style-type: none">• skin rash Chest <ul style="list-style-type: none">• chest pain• shortness of breath Eye and nose <ul style="list-style-type: none">• conjunctivitis (sore, red, gritty or weeping eye/s)• runny nose and eyes General	Speak to your doctor if you have any of these less serious side effects and they worry you.

Less serious side effects	What to do
<ul style="list-style-type: none">• fever Stomach <ul style="list-style-type: none">• upset tummy	

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

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

What Pulmozyme contains

Active ingredient (main ingredient)	dornase alfa
Other ingredients (inactive ingredients)	sodium chloride calcium chloride dihydrate water for injections
Potential allergens	Pulmozyme does not contain gluten, lactose, sucrose, tartrazine or any other azo dyes.

Do not take this medicine if you are allergic to any of these ingredients.

What Pulmozyme looks like

Pulmozyme is a clear, colourless to slightly yellow solution. Pulmozyme comes in packs of 30 ampoules. (AUST R 49822).

Who distributes Pulmozyme

Roche Products Pty Limited
ABN 70 000 132 865
Level 8, 30-34 Hickson Road
Sydney NSW 2000
AUSTRALIA

How to contact us

You can contact us at www.medinfo.roche.com/australia
or by scanning the below code:



You can also call us on 1800 233 950

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

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