



PATIENT INFORMATION LEAFLET

Read all of this leaflet carefully before you start taking/using PULMOZYME

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- This medicine has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

SCHEDULING STATUS

S3

PRODUCT NAME and dosage form

PULMOZYME® (Inhalation solution)

WHAT PULMOZYME CONTAINS

Each PULMOZYME® Inhalation solution ampoule contains 2 500 U (corresponding to 2,5 mg) of dornase alfa per 2,5 ml, corresponding to 1,0 mg/ml dornase alfa.

The other ingredients are sodium chloride, calcium chloride dihydrate and water for injection.

WHAT PULMOZYME 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.

BEFORE YOU USE PULMOZYME

Do not use PULMOZYME if you are allergic (hypersensitive) to:



- Dornase alfa or any of the other ingredients of PULMOZYME (listed in Section 1 above).

Do not use PULMOZYME:

- For children under 5 years of age.
- If you are pregnant, trying to become pregnant or are breastfeeding.

If any of the above apply to you, or if you are not sure, talk to your doctor or pharmacist before you use PULMOZYME.

Pregnancy and breast-feeding

Do not use PULMOZYME if you are pregnant, trying to get pregnant or breast-feeding.

If you are pregnant or breastfeeding your baby while taking PULMOZYME, please consult your doctor, pharmacist or other health care professional for advice.

Driving and using machinery

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

Using other medicines

If you are using other medicines on a regular basis, including complementary or traditional medicines, the use of PULMOZYME with these medicines may cause undesirable interactions. Please consult your doctor, pharmacist or other health care professional for advice.

You can carry on using your usual treatments for cystic fibrosis (such as antibiotics, bronchodilators, pancreatic enzymes, vitamins, corticosteroids and painkillers) when you are using PULMOZYME.

If any of the above apply to you, or if you are not sure, talk to your doctor or pharmacist before you use PULMOZYME.

HOW TO USE PULMOZYME



Always use PULMOZYME exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

PULMOZYME is breathed in (inhaled) using a 'compressed air-driven (jet) nebuliser' (See below 'Which nebuliser to use').

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

People under 5 years of age

PULMOZYME must not be used in children under 5 years of age.

People 5 years of age and over

- You should use PULMOZYME **every day**.
- The usual 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.

If you have the impression that the effect of PULMOZYME is too strong or too weak, talk to your doctor or pharmacist.

Which nebuliser to use:

- Use a compressed air-driven (jet) nebuliser.
- Most types of **ultrasonic nebulisers must not be used**, as they may stop PULMOZYME from working properly.
- 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 the PULMOZYME.

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, or if someone else uses your PULMOZYME ampoules by mistake, talk to a doctor or go to a hospital straight away. Take the medicine pack with you.

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 (two doses at the same time) 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 first if you would like to stop using PULMOZYME.

If someone else uses your PULMOZYME ampoules by mistake, they should talk to a doctor or go to a hospital straight away.

Do not share medicines prescribed for you with another person.

In the event of over dosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.



POSSIBLE SIDE EFFECTS

PULMOZYME can have side effects.

The following effects may occur at any time during your treatment

- Irritation of your eye (conjunctivitis). The signs include redness and itchiness of the eye and a discharge from the eye.
- Changes to your voice including hoarseness or loss of voice.
- Difficulty breathing.
- Sore throat.
- A runny nose or blocked nose and sneezing (rhinitis).
- Cough.
- Upset stomach (indigestion).
- Skin rash, which may be lumpy and itchy (hives).
- Chest pain.
- Fever.
- 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 you are concerned about these or any other unexpected effect(s), talk to your doctor. If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Not all side-effects reported for PULMOZYME are included in this leaflet. Should your general health worsen while taking PULMOZYME, consult your doctor, pharmacist or other health care professional for advice.

STORING AND DISPOSING OF PULMOZYME

- PULMOZYME ampoules must be stored in a refrigerator at 2 – 8 °C.



- The ampoules must be stored in the foil pouch in the outer carton and protected from light (direct sunlight).
- 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).
- The ampoules are for single administration only.
- Keep out of the reach and sight of children.
- Do not use PULMOZYME after the expiry date (EXP) stated on the pack.
- Do not throw away any left over ampoules. Instead, return them to your pharmacist so that they can be disposed of carefully. Only keep them if your doctor tells you to.

PRESENTATION OF PULMOZYME

PULMOZYME is supplied in single use plastic ampoules. Each ampoule contains 2,5 ml of liquid medicine. The ampoules are enclosed in a laminated foil pouch containing 6 ampoules per pouch. Each carton contains 30 PULMOZYME ampoules.

IDENTIFICATION OF PULMOZYME

PULMOZYME inhalation solution is clear and colourless.

REGISTRATION NUMBER

28/30.4/0675

NAME AND ADDRESS OF REGISTRATION HOLDER

Roche Products (Pty) Ltd
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PULMOZYME® (28 0675; Regd)
Dornase alpha (solution)



South Africa

Roche Ethical Assistance Line (REAL) toll-free: 0800 21 21 25

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