

**PATIENT PACKAGE INSERT IN
ACCORDANCE WITH THE PHARMACISTS'
REGULATIONS (PREPARATIONS) – 1986**

The medicine is dispensed with a doctor's prescription only

Pulmozyme®

Solution for Inhalation



Composition:

Each 2.5 ml ampoule contains:
Recombinant Human Deoxyribonuclease (dornase alfa) 2.5 mg (or 2500 U)

For information on inactive ingredients: see section 6 – “Further information”.

Read the leaflet carefully in its entirety before using the medicine. This leaflet contains concise information about the medicine. If you have further questions, refer to the doctor or pharmacist.

This medicine has been prescribed for the treatment of your or your child's ailment. Do not pass it on to others. It may harm them even if it seems to you that their medical condition is similar.

Important information for your attention:

- The medicine Pulmozyme is intended for patients suffering from cystic fibrosis.
- Pulmozyme will generally be given to you together with other medicines for treatment of your or your child's illness (see section 2 – “Drug interactions”).
- Pulmozyme is given by inhalation using a device called a “nebuliser”.
- It is important to confirm that the nebuliser you are using is suitable for Pulmozyme. Please see section 3 – “How should you use the medicine?”.
- Pulmozyme is not intended for children under 5 years of age.
- Keep the medicine in the refrigerator (see section 5 – “How should the medicine be stored?”).

1) WHAT IS THE MEDICINE INTENDED FOR?

The medicine Pulmozyme contains the protein deoxyribonuclease (also referred to as dornase alfa). This protein is a genetically engineered version of a protein found in the body called “DNase”. The medicine Pulmozyme is used to treat people with cystic fibrosis. The medicine aids in breaking down the thick mucous found in the lungs and helps the lungs of cystic fibrosis patients to function better.

The medicine Pulmozyme is intended for inhalation using a device called a “nebuliser”.

In addition to use of Pulmozyme, you will usually continue taking

the other medicines you use to treat cystic fibrosis.

Therapeutic group:

Recombinant human deoxyribonuclease enzyme.

Pulmozyme is a medicine for treatment of cystic fibrosis that acts on the respiratory system.

2) BEFORE USING THE MEDICINE

Do not use Pulmozyme if:

You are sensitive (allergic) to the active ingredient deoxyribonuclease (dornase alfa) or to any of the additional ingredients contained in the medicine (see section 6 – “Further information”).

Special warnings regarding use of the medicine

Consult a doctor or pharmacist before using Pulmozyme.

The medicine is not intended for the treatment of children under 5 years of age. If the medicine has been prescribed for a child under 5 years of age, check with the doctor or pharmacist before use.

Drug interactions

If you are taking, or have recently taken, other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist. Pulmozyme may affect the way other medicines work, and other medicines may affect the way Pulmozyme works. You can carry on using your usual treatments for cystic fibrosis when you are using Pulmozyme (e.g., antibiotics, pancreatic enzymes, bronchodilators and painkillers). If you are uncertain about the combined use, consult the doctor or pharmacist before using the medicine.

Pregnancy, breast-feeding and fertility

Do not use Pulmozyme if you are pregnant, planning to become pregnant or are breast-feeding, unless the doctor has instructed you otherwise.

Driving and operating machinery

The medicine is not likely to affect your ability to drive or operate tools or machinery.

3) HOW SHOULD YOU USE THE MEDICINE?

Always use the preparation according to the doctor's instructions.

Check with the doctor or pharmacist if you are uncertain about the dosage and treatment regimen of the preparation.

Dosage:

The dosage and treatment regimen will be determined by the doctor only.

The usual dosage is generally:

Patients above 5 years of age

- You should use Pulmozyme **every day**.
- The recommended dosage is one ampoule of Pulmozyme every day, by inhalation using the nebuliser.
- If you are over 21 years of age, your doctor may recommend that you use one ampoule twice a day.

Patients under 5 years of age

This medicine is not intended for infants and children under 5 years of age.

Do not exceed the recommended dose.

Method of administration:

The medicine Pulmozyme is administered by inhalation using a nebuliser (see section “Which nebuliser should I use?”). If you are unsure about using it, consult the doctor or pharmacist before starting treatment with the preparation.

Be sure to continue with the routine chest physiotherapy when you are using Pulmozyme.

Which nebuliser should I use?

- Consult the doctor to find out which nebuliser is recommended for use with Pulmozyme.
- **Ultrasonic nebulisers must not be used with Pulmozyme**, as they may prevent the medicine from working properly.
- Read carefully and follow the manufacturer's instructions for use of each nebuliser.

How to use Pulmozyme with the nebuliser?

When you start using the medicine with the nebuliser **please remember these important instructions:**

- Do not mix Pulmozyme with other liquids or other medicines in the nebuliser.
- Do not use any leftover Pulmozyme; it should be thrown away.
- If you have a “re-usable” nebuliser, remember to clean it after use. The manufacturer of the nebuliser will give you the best information regarding instructions for cleaning after using Pulmozyme.
- If someone else accidentally used the preparation, refer him to a doctor as soon as possible.

Use of the nebuliser:

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

If you have accidentally taken a higher dosage, or if a child has accidentally swallowed the medicine, refer immediately to your doctor or proceed to a hospital emergency room, and bring the package of the medicine with you.

If you forgot to take the medicine at the required time, take it as soon as you remember. If you remember when it is nearly time for the next dose, skip the missed dose.

Do not take a double dose to compensate for a forgotten dose.

Adhere to the treatment regimen as recommended by the doctor.

Even if there is an improvement in your health, do not stop treatment with the medicine without consulting the doctor.

If you stop using the medicine

Symptoms related to your lung functioning may get worse. Consult the doctor if you would like to stop using the medicine.

Do not take medicines in the dark! Check the label and the dose each time you take medicine. Wear glasses if you need them. If you have further questions regarding use of the medicine, consult a doctor or pharmacist.

4) SIDE EFFECTS

As with any medicine, use of Pulmozyme may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not suffer from any of them. Side effects as a result of using Pulmozyme are rare and affect less than one in 1,000 patients.

Side effects include:

- Chest pain
- Fever
- Upset stomach (indigestion)
- Voice changes, including hoarseness or loss of voice
- Sore throat
- Breathing difficulties
- A runny or blocked nose and sneezing
- Irritation of the eye (conjunctivitis). The signs include redness and itchiness of the eye and a discharge from the eye
- Skin rashes and itching
- Skin rash, which may be lumpy and itchy
- When you start the treatment, your lung functions may get worse and you may produce more mucous than normal. This effect usually improves with time.

If a side effects occurs, if one of the side effects worsens, or if you suffer from a side effect not mentioned in the leaflet, consult with the doctor.

Reporting side effects

Side effects can be reported to the Ministry of Health by clicking on the link “Report Side Effects of Drug Treatment” found on the Ministry of Health homepage (www.health.gov.il) that directs you to the online form for reporting side effects, or by entering the link: <https://sideeffects.health.gov.il>

5) HOW SHOULD THE MEDICINE BE STORED?

Avoid poisoning! This medicine, and any other medicine, should be kept in a safe place out of the reach and sight of children and/or infants in order to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the doctor.

Do not use the medicine after the expiry date (exp. date) that appears on the package and ampoule. The expiry date refers to the last day of that month.

Storage conditions: Store the preparation refrigerated at 2°C-8°C: This is the temperature range in most home refrigerators. Store the ampoules in the original package to protect from light.

An ampoule that has been left out of the refrigerator only once for no more than 24 hours, at a temperature not exceeding 30°C, can be used.

Do not discard ampoules or their residue in a household waste bin or wastewater. Rather, return them to the pharmacist so they can be safely disposed of to protect the environment. Only keep the ampoules if the doctor has instructed you to do so.

6) FURTHER INFORMATION

In addition to the active ingredient, the medicine also contains:

Sodium chloride, Calcium chloride dihydrate, Water for injection.

What does the medicine look like and what are the contents of the package?

The medicine is provided in clear plastic ampoules.

Each ampoule contains 2.5 ml of solution.

The solution is clear, colorless to slightly yellowish.

The medicine is supplied in packages containing 30 ampoules.

License holder and address: Roche Pharmaceuticals (Israel) Ltd., P.O.B. 6391, Hod Hasharon 4524079.

Manufacturer name and address: F.Hoffmann-La Roche Ltd., Basel, Switzerland.

Revised in May 2022, according to MOH guidelines.

Registration number of the medicine in the National Drug Registry of the Ministry of Health: 101-96-28175-00.

