



Tymbrineb 300 mg/5 ml Nebuliser Solution

tobramycin

Package leaflet:
Information for the user

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.

- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Tymbrineb Nebuliser Solution is and what it is used for
2. What you need to know before you use Tymbrineb Nebuliser Solution
3. How to use Tymbrineb Nebuliser Solution
4. Possible side effects
5. How to store Tymbrineb Nebuliser Solution
6. Contents of the pack and other information

1 What Tymbrineb Nebuliser Solution is and what it is used for

Tymbrineb Nebuliser Solution contains a medicine called tobramycin. This is an aminoglycoside antibiotic.

Tymbrineb Nebuliser Solution is used in patients aged six years and older who have cystic fibrosis to treat chest infections caused by a bacteria called *Pseudomonas aeruginosa*.

Tobramycin fights the infection caused by *Pseudomonas* bacteria in your lungs, and helps to improve your breathing.

When you inhale tobramycin, the antibiotic can get directly into your lungs to fight against the bacteria causing the infection. For the best results of this medicine, use it as this leaflet instructs you.

What is *Pseudomonas aeruginosa*?

This is a very common bacteria that infects nearly everyone with cystic fibrosis at some time during their lives. Some people do not get this infection until later on in their lives, while others get it very young.

This is one of the most damaging bacteria for people with cystic fibrosis. If the infection is not properly controlled, it will continue to damage your lungs causing further problems to your breathing.

Tobramycin kills the bacteria that cause infections in the lungs. The infection can be controlled successfully if the problem is tackled early.

2 What you need to know before you use Tymbrineb Nebuliser Solution

Do not use Tymbrineb Nebuliser Solution:

- if you are allergic to tobramycin, any type of aminoglycoside antibiotic or any of the other ingredients of this medicine (listed in section 6).

If any of the above apply to you, do not use this medicine and talk to your doctor.

If you think you may be allergic, ask your doctor for advice.

Warnings and precautions

Talk to your doctor or pharmacist before using Tymbrineb Nebuliser Solution if you have or if you ever had any of the following conditions:

- Hearing problems (including ringing in your ears and dizziness)
- Kidney problems
- Unusual difficulty in breathing with wheezing or coughing, chest tightness
- Blood in your sputum (the substance you cough up)
- Muscle weakness that lasts or becomes worse in time, symptom mostly related to condition such as myasthenia or Parkinson's disease

If any of these apply to you, tell your doctor before you use Tymbrineb Nebuliser Solution.

Inhaling medicines can cause chest tightness and wheezing and this can happen with tobramycin. Your doctor will supervise your first dose of Tymbrineb Nebuliser Solution and check your lung function before and after dosing. If you are not already doing so, your doctor may ask you to use a bronchodilator, (e.g. salbutamol), before using Tymbrineb Nebuliser Solution.

If you are using Tymbrineb Nebuliser Solution, strains of *Pseudomonas* can become resistant to the treatment over time. This can mean the medicine may not work as well as it should over time. Talk to your doctor if you are concerned about this.

If you have it by an injection, tobramycin can sometimes cause hearing loss, dizziness and kidney damage, and can harm an unborn child.

Children and adolescents

Tymbrineb Nebuliser Solution can be used by children and adolescents aged 6 years and older. It should not be given to children less than 6 years old.

Elderly

If you are aged 65 years and older, your doctor may perform additional tests to decide if Tobramycin Nebuliser Solution is right for you.

Other medicines and Tymbrineb Nebuliser Solution

Tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

You should not take the following medicines while using Tymbrineb Nebuliser Solution:

- Furosemide or ethacrynic acid, diuretics ("water tablets")
- Urea or intravenous mannitol
- Other medicines which may harm your nervous system, kidneys or hearing.

The following medicines can increase the chances of harmful effects occurring if they are given to you while you are receiving **injections** of tobramycin:

- Amphotericin B, cefalotin, ciclosporin, tacrolimus, polymyxins: these medicines may harm your kidneys.
- Platinum compounds (such as carboplatin and cisplatin): these medicines may harm your kidneys or hearing.
- Anticholinesterases (such as neostigmine and pyridostigmine), or botulinum toxin: these medicines may cause muscle weakness to appear or become worse.

If you are taking one or more of the above medicines, discuss with your doctor before you use Tymbrineb Nebuliser Solution.

You should not mix or dilute Tymbrineb Nebuliser Solution with any other medicine in your nebuliser.

If you are taking several different treatments for cystic fibrosis, you should take them in the following order:

1. bronchodilator therapy, such as salbutamol
2. chest physiotherapy
3. other inhaled medicines
4. then Tobramycin Nebuliser Solution.

Please check this order with your doctor as well.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before using this medicine.

Pregnancy

It is not known whether inhaling this medicine when you are pregnant causes side effects.

When they are given by an injection, tobramycin and other aminoglycoside antibiotics can cause harm to an unborn child, such as deafness.

Breast feeding

It is unknown whether inhaled tobramycin can be detected in breast-milk at the recommended dose. If you are breast-feeding your child, you should talk to your doctor before using this medicine.

Driving and using machines

This medicine is not expected to affect your ability to drive and use machines.

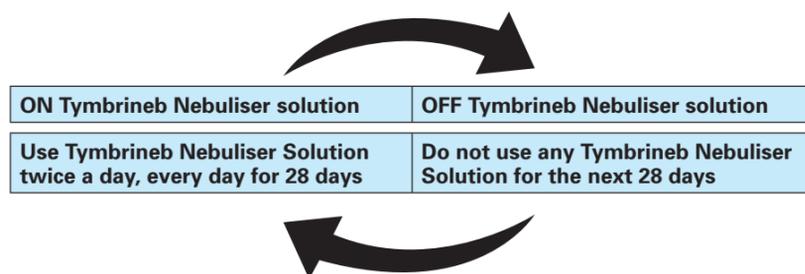
3 How to use Tymbrineb Nebuliser Solution

For inhalation use.

Always use this medicine exactly as your doctor has told you. Check with your doctor if you are not sure.

How much of this medicine you should use and how often you should use it

- The recommended dose is the same for all persons aged 6 years and older.
- Use **two** ampoules each day, for 28 days. Inhale the full contents of one ampoule in the morning, and one in the evening. Ideally, there should be a 12 hour gap between the doses.
- You must leave **at least 6 hours** between two tobramycin inhalations.
- After taking your medicine for 28 days, you then have a 28 day break, where you don't inhale any tobramycin, before starting another course.
- It is important that you keep using the product twice each day during your 28 days on treatment and that you keep to the 28-day on/28-day off cycle.



If you use more Tymbrineb Nebuliser Solution than you should

If you inhale too much tobramycin you may get a very hoarse voice. Make sure you tell your doctor as soon as possible.

If you accidentally swallow Tymbrineb Nebuliser Solution, tell your doctor as soon as possible.

If you forget to use Tymbrineb Nebuliser Solution

If you forget to use Tymbrineb Nebuliser Solution and there are at least 6 hours to your next dose, take your dose as soon as you can. Otherwise, wait for your next dose. Do not double the dose to make up for a forgotten dose.

If you stop using Tymbrineb Nebuliser Solution

You should not stop using Tymbrineb Nebuliser Solution until you have completed the course of treatment or told to do so by your doctor.

Instructions for use of Tymbrineb Nebuliser Solution

This part of the leaflet explains how to use, care and handle Tymbrineb Nebuliser Solution. Please read carefully and follow these instructions.

The equipment you need for inhaling Tymbrineb Nebuliser Solution

Tymbrineb Nebuliser Solution should be used with a clean, dry PARI LC PLUS reusable nebuliser and a suitable compressor. Ask your doctor or physiotherapist for advice on which compressor to use. Your doctor or physiotherapist can advise you on the proper use of your medicine and the equipment you need. You may need different nebulisers for your other inhaled medicines for cystic fibrosis.

Before you start to use Tymbrineb Nebuliser Solution, make sure you have the following pieces of equipment:

- Tobramycin ampoule
- PARI LC PLUS reusable nebuliser
- Suitable compressor
- Tubing to connect the nebuliser and compressor
- Clean paper or cloth towels
- Nose clips (if required)

You should check that your nebuliser and compressor are working properly according to the manufacturer's instructions before you start to use your medicine.

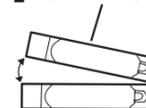
Preparing your medicine for inhalation

1. Wash your hands thoroughly with soap and water.



2. Each foil pouch contains 4 ampoules. Cut or tear open the pouch, remove an ampoule and put the foil pouch in the refrigerator.

2 pair of ampoules

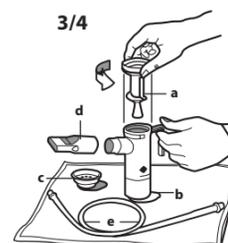


3. Lay out the pieces of your PARI LC PLUS nebuliser on a clean, dry paper or cloth towel.

You should have the following pieces:

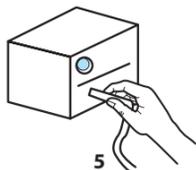
- a. Nebuliser top
- b. Nebuliser bottom
- c. Inspiratory valve cap
- d. Mouthpiece with valve
- e. Tubing

3/4

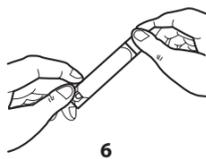


4. Remove the nebuliser top from the nebuliser bottom by twisting the top anticlockwise and then lifting it. Place the top on the towel and stand the nebuliser bottom upright on the towel.

5. Connect one end of the tubing to the compressor air outlet. Make sure that the tubing fits snugly and plug the compressor into the electrical outlet.



6. Open the ampoule by holding the bottom tab with one hand and twisting off the top with your other hand. Be careful not to squeeze the ampoule until you are ready to empty it into the nebuliser bottom.



7. When you are ready, squeeze all of the contents of the ampoule into the nebuliser bottom.



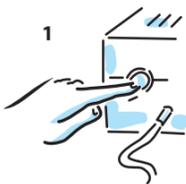
8. Replace the nebuliser top. Turn the top clockwise until it is securely fastened to the nebuliser bottom.

9. Attach the mouthpiece to the nebuliser outlet. Firmly push the inspiratory valve cap in place on the nebuliser top. The inspiratory valve cap must fit snugly (check with your PARI LC PLUS nebuliser leaflet).

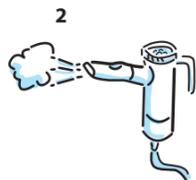
10. Connect the free end of the tubing to the air intake on the bottom of the nebuliser, making sure you keep the nebuliser upright. Press the tubing on the air intake firmly.

Taking your medicine

1. Turn on the compressor.



2. Make sure there is a steady mist coming from the mouthpiece. If there is no mist, check that all the tubing connections and that the compressor is working correctly.



3. Sit or stand in an upright position so that you can breathe normally.



4. Place the mouthpiece between your teeth and on top of your tongue. Breathe through your mouth (you may find that nose clips help). Try not to block the airflow with your tongue.
5. Continue until all of the Tymbrineb Nebuliser Solution is gone and there is no longer any mist being produced.
6. **Please remember to clean and disinfect your nebuliser after treatment. You should never use a dirty or clogged nebuliser. You should not share your nebuliser with other people.**

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4 Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Some side effects can be serious

If you experience any of the following, stop using Tymbrineb Nebuliser Solution and **tell your doctor straight away**:

- Unusual difficulty in breathing with wheezing or coughing and chest tightness
- Allergic reactions including hives and itching

If you experience any of the following, **tell your doctor straight away**:

- Loss of hearing (ringing in the ears is a potential warning sign of hearing loss), noises (such as hissing) in the ears

Your underlying lung disease may worsen while you are using Tymbrineb Nebuliser Solution. This may be due to a lack of efficacy. Tell your doctor straight away if this happens.

Very common (may affect more than 1 in 10 people)

- Runny or stuffy nose, sneezing
- Voice alteration (hoarseness)
- Discolouration of the substance you cough up (sputum)
- Lung disorder
- Worsening of lung function test results

If any of these affects you severely, **tell your doctor**.

Common (may affect up to 1 in 10 people)

- Generally feeling unwell
- Muscle pain
- Voice alteration with sore throat and difficulty swallowing (laryngitis)

If any of these affects you severely, **tell your doctor**.

Other side effects

- Itching
- Itchy rash
- Rash
- Ear pain
- Loss of the voice
- Disturbed sense of taste
- Sore throat

If any of these affects you severely, **tell your doctor**.

If you have used Tymbrineb Nebuliser Solution at the same time as or following repeated courses of tobramycin or another aminoglycoside antibiotic by injection, hearing loss has been reported as a side effect. Injections of tobramycin or other aminoglycosides can cause allergic reactions, hearing problems and kidney problems.

People with cystic fibrosis have many symptoms of the disease. These may still happen while using Tymbrineb Nebuliser Solution, but should not be any more frequent or seem worse than before.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRC Pharmacovigilance, Website: www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5 How to store Tymbrineb Nebuliser Solution

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the outer packaging, pouch and ampoule after EXP. The expiry date refers to the last day of that month.

Store in a refrigerator (2 °C – 8 °C). Do not freeze. You can store the foil pouches (opened or unopened) at room temperature (do not store above 25 °C) for up to 28 days. Store in the original package in order to protect from light. **Never store an opened ampoule. Once opened an ampoule should be used immediately, and any remaining product should be discarded.**

Do not use this medicine if you notice any visible signs of deterioration (cloudiness or bits in the solution). Tobramycin solution may be slightly yellow and some variability in colour may be observed; this does not indicate loss of activity providing the solution has been stored as recommended.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6 Contents of the pack and other information

What Tymbrineb Nebuliser Solution contains

- The active substance is tobramycin. Each 5 ml single dose ampoule contains 300 mg of tobramycin.
- The other ingredients are: sodium chloride, water for injections, sulfuric acid (for pH-adjustment) and sodium hydroxide (for pH-adjustment).

What Tymbrineb Nebuliser Solution looks like and contents of the pack

Tymbrineb Nebuliser Solution is a clear to slightly yellow solution.

Tymbrineb Nebuliser Solution is supplied in 5 ml, single dose ampoules.

4 ampoules are packed and sealed in a foil pouch. Each carton comprises 14 (56 ampoules), 28 (112 ampoules) or 42 (168 ampoules) foil pouches, which is enough to last one, two or three cycles of treatment, respectively.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:

Teva Pharma B.V.
Swensweg 5
2031GA Haarlem
The Netherlands

Manufacturer:

Pharmachemie B.V.,
Swensweg 5,
2031 GA Haarlem,
The Netherlands

Or

Merckle GmbH,
Ludwig-Merckle-Str. 3,
89143 Blaubeuren,
Germany

Or

Norton Healthcare Limited T/A IVAX Pharmaceuticals UK,
Preston Brook,
Runcorn
Cheshire,
WA7 3FA,
United Kingdom

This medicine is authorised in the Member States of the European Economic Area and in the United Kingdom (Northern Ireland) under the following names:

Denmark	Tobramycin TEVA
Germany	Tobramycin Teva 300 mg/5 ml Steri-Neb Lösung für einen Vernebler
Ireland	Tymbrineb 300 mg/5 ml Nebuliser Solution
Italy	Tobramicina Teva 300 mg/5 ml soluzione per nebulizzatore
Portugal	Tobramicina Teva
Spain	Tobramicina Teva 300 mg/5 ml solución para inhalación por nebulizador
The Netherlands	Tobramycine Steri-Neb 300 mg/5 ml verneveloplossing
United Kingdom (Northern Ireland)	Tymbrineb 300 mg/5 ml Nebuliser Solution

This leaflet was last revised in September 2021.