

Package leaflet: Information for the patient

Tobramycin 300 mg/ 5 ml nebuliser solution tobramycin

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

1. What Tobramycin is and what it is used for

Tobramycin contains an antibiotic medicine called tobramycin. It belongs to a class of antibiotic medicines called aminoglycosides.

Tobramycin is used in patients aged 6 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 while 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 Tobramycin

Do NOT use Tobramycin

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

If any of above applies 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 before using Tobramycin if you have or if you have 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 worsens with time, for example symptoms related to conditions such as myasthenia (muscle weakness) or Parkinson's disease
- if you or your family members have a mitochondrial mutation disease (condition caused by variants in the genome of mitochondria, the parts of your cells which help make energy) or loss of hearing due to antibiotic medicines; certain mitochondrial mutations may increase your risk of hearing loss with this product.

If any of these apply to you, tell your doctor before you use Tobramycin.

Inhaling medicines can cause chest tightness and wheezing and this can happen with Tobramycin. Your doctor will supervise your first dose of Tobramycin 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 Tobramycin.

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

Children and adolescents

Tobramycin can be used by children and adolescents aged 6 years and older. Tobramycin 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 is right for you.

Other medicines and Tobramycin

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

You should **NOT** take the following medicines while you are using Tobramycin

- furosemide or ethacrynic acid, diuretics ('water tablets')
- other medicines which may affect kidney function such as 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, ceftazidime, ciclosporin, polymyxins (used to treat microbial infections), tacrolimus (used to reduce the activity of immune system). These medicines may harm your kidneys
- platinum compounds such as carboplatin and cisplatin (used to treat some forms of cancer). These medicines may harm your kidneys or hearing
- anticholinesterases such as neostigmine and pyridostigmine (used to treat muscle weakness), 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 this with your doctor before you use Tobramycin.

You should not mix or dilute Tobramycin with any other medicines in your nebuliser handset.

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.

Please check this order with your doctor as well.

Pregnancy and breast-feeding

Pregnancy

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

It is not known whether inhaling this medicine when you are pregnant causes side effects. When given as an injection, tobramycin and other aminoglycoside antibiotics can cause harm to an unborn child, such as deafness.

Breast-feeding

If you are breast-feeding your child, you should talk to your doctor before using this medicine.

Driving and using machines


Tobramycin should not affect your ability to drive and use machines.

3. How to use Tobramycin

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

The recommended dose is **two** ampoules each day (one in the morning and one in the evening) for 28 days.

- the recommended dose is the same for all persons aged 6 years and older
- inhale by mouth the full contents of one ampoule in the morning and one ampoule in the evening using the nebuliser handset
- it is best to have an interval as close as possible to 12 hours between the doses, but this interval must be **at least 6 hours**
- after you have used your medicine for 28 days, you then have a 28-day break, during which you do not inhale any Tobramycin. You then start another course after the break (as illustrated)
- it is important that you keep using the medicine twice each day during your 28 days on treatment and that you keep to the **28-day on, 28-day off cycle**



On Tobramycin	Off Tobramycin
Use Tobramycin twice a day, every day for 28 days	Do not use any Tobramycin for the next 28 days



Repeat cycle

Continue using Tobramycin on this cyclical basis for as long as your doctor tells you. If you have questions about how long to use Tobramycin, talk to your doctor or pharmacist.

Instructions for use of Tobramycin

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

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

The equipment you need for inhaling Tobramycin

Tobramycin should be used with a clean and dry reusable nebuliser.

The LC PLUS nebuliser (manufactured by PARI GmbH) is suitable for use with Tobramycin.

Your doctor or physiotherapist can advise you on the proper use of Tobramycin and the equipment you need. You may need different nebulisers for your other inhaled medicines for cystic fibrosis.

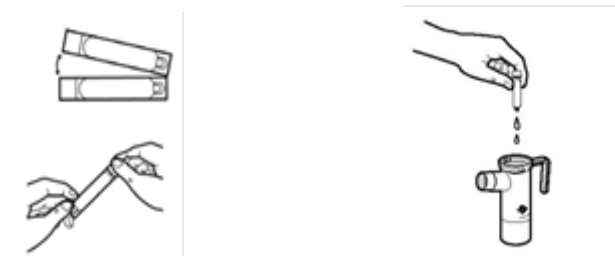
Preparing to inhale Tobramycin

- wash your hands thoroughly with soap and water
- each foil pouch contains 4 ampoules. Cut or tear open the pouch. Remove one ampoule of Tobramycin from the aluminium pouch. Keep the rest of the medicine refrigerated in the original carton
- lay out all the pieces of your nebuliser on a clean, dry paper or cloth towel
- make sure you have a suitable compressor and tubing to connect the nebuliser to the compressor
- be careful to follow the appropriate instructions for use for your type of nebuliser, you must read the leaflet provided by the manufacturer. Check that your nebuliser and compressor are working properly according to the manufacturer's instructions before you start to take your medicine.

Use of Tobramycin with LC PLUS (PARI GmbH)

For more detailed instructions on the use and care of the nebuliser, please read the leaflet provided with the PARI LC PLUS.

1. Remove the nebuliser top from the nebuliser by twisting the top anticlockwise and then lifting it. Place the top on the towel and stand the nebuliser chamber upright on the towel
2. Connect one end of the tubing to the compressor air outlet. Make sure that the tubing fits snugly. Plug the compressor into the electrical outlet
3. Open the Tobramycin ampoule by holding the bottom tab with one hand and twisting off the top with your other hand. Squeeze all the contents of the ampoule into the nebuliser chamber



4. Replace the nebuliser top, put the mouthpiece and the inspiratory valve cap in place on the nebuliser, and connect the compressor as indicated in your PARI LC PLUS nebuliser leaflet
5. Turn on the compressor. Check that there is steady mist coming from the mouthpiece. If there is no mist, check all tubing connections and that the compressor is working properly
6. Sit or stand in an upright position so that you can breathe normally

7. Place the mouthpiece between your teeth and on top of your tongue. Breathe normally, but only through your mouth (you may use a nose clip if your doctor agrees). Try not to block the airflow with your tongue



8. Continue until all of the Tobramycin is gone and there is no longer any mist being produced. It should take about 15 minutes to take all the treatment. You may hear a spluttering sound when the nebuliser cup is empty.
9. Please remember to clean and disinfect your nebuliser after treatment according to the manufacturer's instructions. You should never use a dirty or clogged nebuliser. You should not share your nebuliser with other people.

If you are interrupted, or need to cough or rest during your treatment, turn off the compressor to save your medicine.

Turn the compressor on again when you are ready to restart your treatment. Leave out this dose if your next dose is due in less than 6 hours.

If you use more Tobramycin 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 Tobramycin is swallowed, tell your doctor as soon as possible.

If you forget to use Tobramycin

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

If you stop using Tobramycin

Do not stop using Tobramycin unless your doctor tells you to do so, as your lung infection may not be controlled sufficiently and may become worse.

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.

Serious side effects

Stop using Tobramycin and tell your doctor immediately about any of the following serious side effects:

- unusual difficulty in breathing with wheezing or coughing and chest tightness
- allergic reactions including hives and itching

Tell your doctor immediately about any of the following serious side effects:

- 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 Tobramycin. This may be due to a lack of effect. Tell your doctor straight away if this happens.

Other side effects

Tell your doctor as soon as possible about any of the following side effects:

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

- runny or stuffy nose, sneezing
- voice alteration (hoarseness)
- discoloration of the substance you cough up (sputum)
- worsening of lung function test results

Common (may affect up to 1 in 10 users)

- generally feeling unwell
- muscle pain
- voice alteration with sore throat and difficulty swallowing (laryngitis)

Other side effects

- itching
- itchy rash
- rash
- loss of the voice
- disturbed sense of taste
- sore throat

Not known (frequency cannot be estimated from the available data)

- increased quantity of the substance you cough up (sputum)
- chest pain
- reduced appetite.

If you use Tobramycin 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 Tobramycin, 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 the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Tobramycin

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 label or the pouch or carton after EXP. The expiry date refers to the last day of that month.

Store in a refrigerator (2°C -8°C). If you don't have a refrigerator available (such as when you are transporting your medicine) you can store the carton with the medicines (pouches opened or unopened) below 25°C for up to 28 days. Do not use Tobramycin ampoules which have been stored at room temperature for more than 28 days.

Store your ampoules in the original package in order to protect from light. This medicine is normally colourless to light yellow but this can vary and sometimes it can be a darker yellow. This does not change the way this medicine works provided that the storage instructions have been followed.

Do not use this medicine if you notice that it has gone cloudy, or if there are bits in the solution.

Never store an opened ampoule. Once opened an ampoule should be used immediately and any remaining product should be discarded.

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 Tobramycin contains

- The active substance is tobramycin. Each ampoule of 5 ml contains 300 mg tobramycin, corresponding to 60 mg/ml.
- The other ingredients are: sodium chloride, water for injection, nitrogen (E941), sulfuric acid (E513) (for pH adjustment) and/or sodium hydroxide (E524) (for pH adjustment).

What Tobramycin looks like and contents of the pack

Tobramycin nebuliser solution is a clear, colourless to light yellow solution free from visible particulate matter.

Tobramycin is provided in a ready-to-use ampoule. Ampoules are packed in foil pouches, one foil pouch contains 4 ampoules which corresponds to 2 days of treatment.

Tobramycin is available in packs of 56, 112 or 168 ampoules, which is enough to last one, two or three cycles of treatment, respectively.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

Sun Pharmaceutical Industries Europe B.V.
Polarisavenue 87
2132 JH Hoofddorp
The Netherlands

Manufacturer

Sun Pharmaceutical Industries Europe B.V.
Polarisavenue 87
2132 JH Hoofddorp
The Netherlands

S.C. Terapia S.A.
124 Fabricii Street
400632, Cluj-Napoca
Cluj County
Rumania

This medicinal product is authorised in the Member States of the EEA under the following names

Germany:	Tobramycin SUN 300 mg Lösung für einen Vernebler
Denmark:	Tobramycin SUN 300 mg/ 5 ml inhalationsvæske til nebulisator, opløsning
Spain:	Tobramicina SUN 300 mg/ 5 ml solución para inhalación por nebulizador
France:	Tobramycine SUN 300 mg/ 5 ml solution pour inhalation par nébuliseur
Italy:	Tobramicina SUN 300 mg/ 5 ml soluzione per nebulizzatore
Netherlands:	Tobramycine SUN 300 mg/ 5 ml verneveloplossing
Poland:	Tobramycyna SUN 300 mg/ 5 ml roztwór do nebulizacji

Romania: Tobramicină SUN 300 mg/ 5 ml soluție pentru nebulizator
United Kingdom (NI): Tobramycin 300 mg/ 5 ml nebuliser solution

This leaflet was last revised in 09/2021