

Package leaflet: Information for the patient

Tobramycine Aristo 300 mg/ 5 ml verneveloplossing 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 Tobramycine Aristo is and what it is used for
2. What you need to know before you use Tobramycine Aristo
3. How to use Tobramycine Aristo
4. Possible side effects
5. How to store Tobramycine Aristo
6. Contents of the pack and other information

1. What Tobramycine Aristo is and what it is used for

Tobramycine Aristo contains a medicine called tobramycin. This is an aminoglycoside antibiotic.

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

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

When you inhale Tobramycine Aristo, 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.

Tobramycine Aristo 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 Tobramycine Aristo

Do not use Tobramycine Aristo:

- 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 take 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 taking Tobramycine Aristo 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 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 take Tobramycine Aristo.

If you or your maternal family members have a mitochondrial mutation disease (a genetic condition) or loss of hearing due to antibiotic medicines, you are advised to inform your doctor or pharmacist before you take this medicine; certain mitochondrial mutations may increase your risk of hearing loss with this product. Your doctor may recommend genetic testing before administration of Tobramycine Aristo.

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

If you are taking Tobramycine Aristo, 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

Tobramycine Aristo can be taken by children and adolescents aged 6 years and older. Tobramycine Aristo 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 Tobramycine Aristo is right for you.

Other medicines and Tobramycine Aristo

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 taking Tobramycine Aristo:

- 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 take Tobramycine Aristo.

You should not mix or dilute Tobramycine Aristo 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 Tobramycine Aristo

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 for advice before taking this medicine.

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.

Driving and using machines

Tobramycine Aristo should not affect your ability to drive and use machines.

Tobramycine Aristo contains sodium

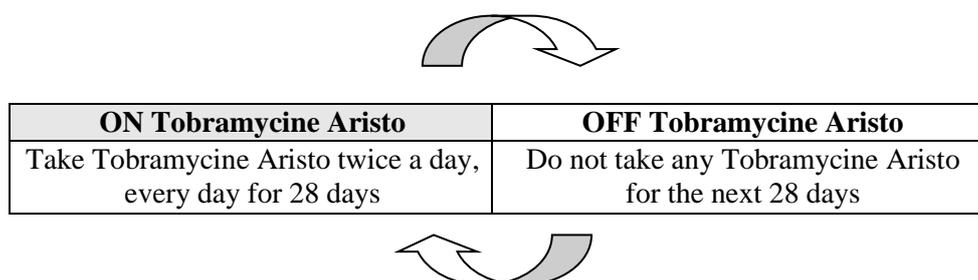
This medicine contains less than 1 mmol sodium (23 mg) per ampoule, that is to say essentially “sodium-free”.

3. How to use Tobramycine Aristo

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

How much of this medicine you should take and how often you should take 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 Tobramycine Aristo inhalations.
- After taking your medicine for 28 days, you then have a 28 day break, where you don’t inhale any Tobramycine Aristo, 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**.



Repeat cycle

If you take more Tobramycine Aristo than you should

If you inhale too much Tobramycine Aristo you may get a very hoarse voice. Make sure you tell your doctor as soon as possible. If Tobramycine Aristo is swallowed, tell your doctor as soon as possible.

If you forget to take Tobramycine Aristo

If you forget to take Tobramycine Aristo 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 take a double dose to make up for the missed dose.

Instructions for use of Tobramycine Aristo.

This part of the leaflet explains how to use, care and handle Tobramycine Aristo. 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 Tobramycine Aristo

Tobramycine Aristo should be used with a clean and dry reusable nebuliser.

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

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

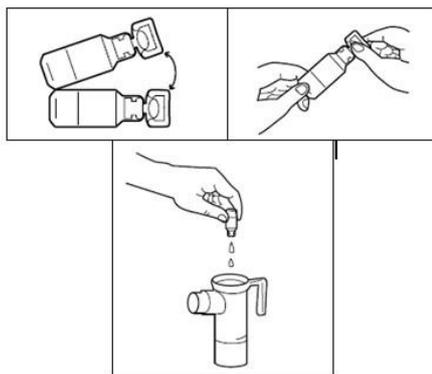
Preparing to inhale Tobramycine Aristo

- Wash your hands thoroughly with soap and water.
- Each Tobramycine Aristo foil pouch contains 7 ampoules. Cut or tear open the pouch. Remove one Tobramycine Aristo ampoule from the tray by gently pulling apart from any attached ampoules at the bottom tabs. Put the remaining ampoules back in the foil pouch and keep them in the refrigerator.
- Lay out all the pieces of your nebuliser on a clean, dry paper or cloth towel.
- Make sure you have the suitable compressor, and tubing to connect the nebuliser and compressor.
- Be careful to follow the appropriate instructions for use for your type of nebuliser, you must read the leaflet provided with the nebuliser 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.

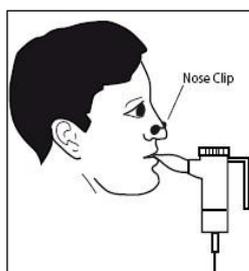
Use of Tobramycine Aristo with LC PLUS (PARI GmbH)

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 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.
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 Tobramycine Aristo 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 bottom.



4. Replace the nebuliser top, put the mouthpiece and the inspiratory valve cap in place on the nebuliser, then connect the compressor as indicated in your PARI LC PLUS nebuliser leaflet.
5. Turn on the compressor. Check that there is a 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 Tobramycine Aristo 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 have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, Tobramycine Aristo can cause side effects, although not everybody gets them.

Some side effects can be serious

If you experience any of the following, stop taking Tobramycine Aristo 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 taking Tobramycine Aristo. This may be due to a lack of efficacy. Tell your doctor straight away if this happens.

Some side effects are very common

These side effects may affect more than 1 in 10 people.

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

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

Some side effects are common

These side effects 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
- loss of the voice
- disturbed sense of taste
- sore throat

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

If you have had Tobramycine Aristo 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 taking Tobramycine Aristo, 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 or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the **national reporting system** listed in [Appendix V](#). By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Tobramycine Aristo

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 carton, overpouch or ampoule. The expiry date refers to the last day of that month.

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

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 foil pouches (opened or unopened) at room temperature (not above 25°C) for up to 28 days.

Do not use Tobramycine Aristo ampoules which have been stored at room temperature for more than 28 days.

This medicine is normally a slightly yellow colour 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.

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 to protect the environment.

6. Contents of the pack and other information

What Tobramycine Aristo contains

- The active substance is tobramycin. One 5 ml ampoule contains 300 mg of tobramycin as a single dose.
- The other ingredients are sodium chloride, water for injections as well as sodium hydroxide (E524) and sulphuric acid (E513) (for adjusting the level of acidity).

What Tobramycine Aristo looks like and contents of the pack

Tobramycine Aristo is a clear, slightly yellow solution that comes in a ready-to-use ampoule.

Ampoules are packed in foil pouches, one foil pouch contains 7 ampoules.

Tobramycine Aristo is available in packs of 56 ampoules, which is enough to last one cycle of treatment.

Marketing Authorisation Holder

Aristo Pharma GmbH
Wallenroder Str. 8-10
13435 Berlijn
Duitsland

Manufacturer

MEDICHEM, S.A.
Narcís Monturiol, 41 A, Sant Joan Despí
08970 Barcelona
Spain

Marketing Authorisation Number(S)

RVG 121938

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

Germany: Tobramycin Aristo 300 mg/ 5 ml Lösung für einen Vernebler
Netherlands: Tobramycine Aristo, 300 mg/5 ml verneveloplossing
United Kingdom (Northern Ireland): Munuza 300 mg/5 ml nebuliser solution

Deze bijsluiter is voor het laatst goedgekeurd in september 2023.