

Consumer Medicine Information

TOBRAMYCIN BNM

Tobramycin

Solution for inhalation 300 mg/5 ml

What is in this leaflet

Please read this leaflet carefully before you start using Tobramycin BNM.

This leaflet answers some common questions about Tobramycin BNM. It does not contain all the available information. The most up-to-date Consumer Medicine Information can be downloaded from www.medsafe.govt.nz. Those updates may contain important information about the medicine and its use of which you should be aware.

Reading this leaflet does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you using Tobramycin BNM against the benefits this medicine is expected to have for you.

If you have any concerns about using this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may want to read it again.

What Tobramycin BNM is used for

Tobramycin BNM contains an antibacterial agent, tobramycin, which is active against a common lung infection that occurs in patients with cystic fibrosis (CF).

Tobramycin belongs to a class of antibiotics called aminoglycosides. It works by killing or stopping the growth of the bacteria that cause the infection.

The bacterium that commonly infects the lungs of most cystic fibrosis patients at some stage of their lives is *Pseudomonas aeruginosa*. It is one of the most damaging bacteria for people with CF.

Some people do not get this infection until later on in their lives, while others get it very young. If the infection is not properly fought, it will continue to damage your lungs, causing further problems with your breathing.

Tobramycin BNM solution is for administration by inhalation via a nebuliser and compressor. When you inhale Tobramycin BNM, the antibiotic can get straight into your lungs to fight against the infection and to improve your breathing.



For best results, please use Tobramycin BNM as this leaflet instructs you.

Although Tobramycin BNM does not cure your condition, it does help control it.

Tobramycin BNM is not recommended for use in children younger than 6 years of age.

Your doctor may have prescribed this medicine for another reason.

Ask your doctor if you have any questions about why Tobramycin BNM has been prescribed for you.

Tobramycin BNM is only available with a doctor's prescription.

Tobramycin BNM is not addictive.

Before you use Tobramycin BNM

Tobramycin BNM is not suitable for everyone.

When you must not use it

Do not use Tobramycin BNM if you have an allergy to:

- Tobramycin BNM or any other tobramycin medicine, e.g. Nebcin®
- any antibiotics that belong to the aminoglycoside group (e.g. amikacin, gentamicin, neomycin or streptomycin).
- any of the other ingredients listed at the end of this leaflet.

The symptoms of an allergic reaction may include:

- skin rash, itchiness
- shortness of breath, wheezing or difficulty breathing
- swelling of the lips, tongue, face or other parts of the body.

Do not use Tobramycin BNM if you think you may be allergic to it, ask your doctor for advice.

Do not use it after the expiry date 'EXP' printed on the pack.

If you use it after the expiry date has passed, it may not work as well.

Do not use it if the packaging is torn or shows signs of tampering. In that case, return it to your pharmacist.

Do not give Tobramycin BNM to a child below the age of 6, unless directed to by the child's doctor or pharmacist.

Tobramycin BNM is not recommended for use in children under 6 years.

If you are not sure whether you or your child should start using Tobramycin BNM, talk to your doctor or pharmacist.

Before you start to use it



Tell your doctor if you are pregnant or intend to become pregnant.

Tobramycin BNM may affect your developing baby if you use it during pregnancy. Your doctor or pharmacist will discuss the possible risks and benefits of using Tobramycin BNM during pregnancy.

Tell your doctor if you are breast-feeding or plan to breast-feed.

Your baby may absorb this medicine from breast milk and therefore there is a possibility of harm to the baby. Your doctor or pharmacist will discuss the risks and benefits of using Tobramycin BNM during breast-feeding.

Tell your doctor if you have or have had any medical conditions, especially the following:

- kidney problems
- hearing problems, including noises in the ears and dizziness
- unusual difficulty in breathing with wheezing or coughing, chest tightness
- trouble with your balance
- dizzy spells
- problems with nerve or muscle function
- muscle weakness that lasts, or becomes worse in time, a symptom mostly related to conditions such as Parkinson's disease (a condition of the brain affecting movement) or myasthenia (a condition in which the muscles become weak and tire easily).

Tell your doctor or pharmacist if you have allergies to any other medicines, foods, preservatives or dyes.

Your doctor will want to know if you are prone to allergies.

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

If you have not told your doctor or pharmacist about any of the above, tell them before you start using Tobramycin BNM.

Taking other medicines

Tell your doctor or pharmacist if you are using or have recently taken any other medicines, including any that you buy without a prescription from your pharmacy, supermarket or health food shop.

Tell any healthcare professional who is prescribing a new medicine for you that you are using Tobramycin BNM.

Some medicines and Tobramycin BNM may interfere with each other. These include:

- diuretics (fluid tablets), especially those that contain frusemide or ethacrynic acid
- urea
- mannitol given by injection
- dornase alfa, a medicine used to treat cystic fibrosis (CF)
- inhaled corticosteroid, a medicine that is inhaled to act directly on your air passages to improve or prevent asthma attacks from occurring
- certain antibiotics such as tobramycin or another aminoglycoside antibiotic given by injection (e.g. amikacin, gentamicin, neomycin, streptomycin)
- any other medicine that can cause damage to the nerves, kidneys or the ears.



The above medicines may be affected by Tobramycin BNM or may affect how well it works. You may need different amounts of Tobramycin BNM, or take it at different times, or you may need to take different medicines. Your doctor or pharmacist will advise you.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while using Tobramycin BNM.

How to use Tobramycin BNM

Read the label carefully and follow all directions given to you by your doctor and pharmacist.

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the pack, ask your doctor or pharmacist for help.

How much to use

Inhale Tobramycin BNM only when prescribed by your doctor.

Do not exceed the recommended dose.

The recommended dose of Tobramycin BNM is one 300 mg/5 mL ampoule twice daily (every 12 hours) for 28 days.

This is followed by 28 days of not inhaling Tobramycin BNM. Repeat the 28 day on drug / 28 day off drug cycle.

Ask your doctor or pharmacist if you are unsure of the correct dose for you.

They will tell you exactly how much to use. This depends on your condition and whether or not you are taking any other medicines.

If you take the wrong dose, Tobramycin BNM may not work as well and your problem may not improve.

How to use it

Tobramycin BNM solution is contained in a ready-to-use ampoule. It is for inhalation therapy using a PARI LC PLUS reusable nebuliser.

It is important that your nebuliser and compressor function properly before you start your Tobramycin BNM therapy.

Breathe normally through the mouthpiece of the nebuliser until all of the Tobramycin BNM solution is gone and there is no longer any mist being produced.

This is usually for a period of approximately 15 minutes. You may sit or stand upright while inhaling your dose.

If you are not sure how to use a nebuliser, ask your doctor or pharmacist.



Children should only use a nebuliser on medical advice and with the help of an adult.

When to use it

Please check the order of medications with your doctor.

If you are using several different inhaled treatments and performing therapies for cystic fibrosis, you should use Tobramycin BNM LAST.

Use Tobramycin BNM at about the same time every day.

Using your medicine at the same time each day will help you remember when to inhale it.

Inhale Tobramycin BNM twice daily.

Doses should be administered as close to 12 hours apart as possible and not less than 6 hours apart.

How to inhale Tobramycin BNM

Preparing to inhale Tobramycin BNM

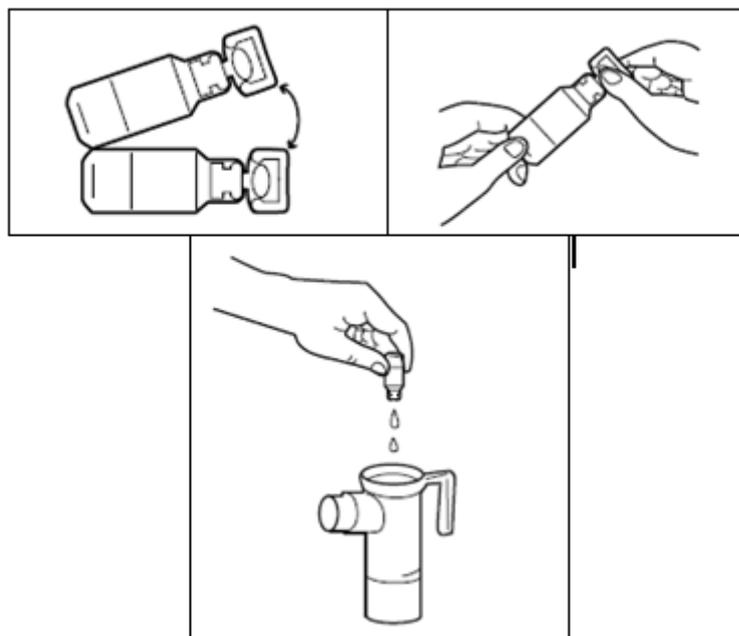
1. Wash your hands thoroughly with soap and water.
2. Each Tobramycin BNM foil pouch contains 7 ampoules. Cut or tear open the pouch. Remove one Tobramycin BNM ampoule from the pouch. Put the remaining ampoules back in the foil pouch and keep them in the refrigerator.
3. Lay out all the pieces of your nebuliser on a clean and dry paper or cloth towel.
4. Make sure you have the suitable compressor and tubing to connect the nebuliser and compressor.
5. Be careful to follow the appropriate instructions for use for your type of nebuliser. You must read the instructions 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 use your medicine.

Use of Tobramycin BNM with the PARI LC PLUS nebuliser

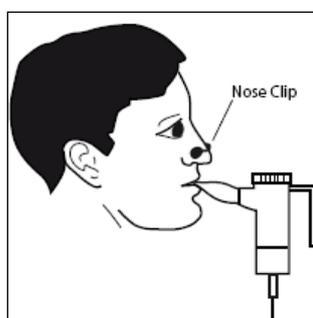
For more detailed instructions on the use of the nebuliser, please read the instructions provided with the PARI LC PLUS.

1. Remove the nebuliser top from the nebuliser bottom by twisting the top anticlockwise and then lifting it. Place the top on a clean, dry 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 Tobramycin BNM 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 the instructions provided with the PARI LC PLUS nebuliser.
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. Try not to block the airflow with your tongue. You can use a nose clip if your doctor tells you to.



8. Continue until all of the Tobramycin BNM is gone and there is no longer any mist being produced. It should take about 15 minutes to inhale 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.

How long to use it

Use Tobramycin BNM twice daily every day for 28 days, followed by a 28 day period off Tobramycin BNM. Continue using Tobramycin BNM in these 28 day on / 28 day off cycles for as long as your doctor or pharmacist tells you.

If you are unsure about how long to use Tobramycin BNM, talk to your doctor or pharmacist.

If you forget to use it

If there are at least 6 hours to your next dose, use Tobramycin BNM and then go back to using your medicine as you would normally.

If it is almost time for your next dose, skip the dose you missed and have your next dose when you are meant to.

Do not have a double dose to make up for the dose that you missed.

This may increase the chance of getting an unwanted side effect.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering to use your medicine, ask your pharmacist for hints.

While you are using Tobramycin BNM

Things you must do

Keep Tobramycin BNM in the foil pouch (when the foil is opened or unopened) in the pack until it is time for your dose and keep them in the refrigerator.

If you take the medication out of the pouch it will not keep well.

Consult the instructions for your inhalation equipment for detailed information and diagrams describing their correct use and care.

If you are interrupted or need to cough or rest during your Tobramycin BNM treatment, turn off the compressor to save your medicine. Turn the compressor on again when you are ready to restart your treatment.

If you are about to be started on any new medicine, tell your doctor and pharmacist that you are using Tobramycin BNM. Likewise, tell any other doctors, dentists and pharmacists who are treating you that you are using this medicine.



If you are going to have surgery, tell the surgeon and anaesthetist that you are using this medicine.

It may affect other medicines used during surgery.

If you become pregnant while using this medicine, tell your doctor immediately.

See your doctor if you feel that your condition is not improving or is getting worse.

Things you must not do

Do not use this medicine if the solution is cloudy or if there are particles in the solution.

Do not use any Tobramycin BNM which you have stored at room temperature for more than 28 days.

Do not dilute or mix other medications with Tobramycin BNM in the nebuliser.

Never use a dirty or clogged nebuliser. Do not share your nebuliser with other people.

Do not give your medicine to anyone else, even if they have the same condition as you.

This medicine is only intended for the person it has been prescribed for.

Do not use Tobramycin BNM to treat any other complaints unless your doctor tells you to.

Do not stop using Tobramycin BNM or change the dosage without checking with your doctor or pharmacist.

Things to be careful of

Inhaling medicines can cause chest tightness and wheezing. This may happen immediately after inhaling this medicine.

If you have swallowed Tobramycin BNM in error, tell your doctor as soon as possible.

When swallowed, this medicine will not harm you, but this medicine will not work as it is meant to.

Be careful driving or operating machinery until you know how Tobramycin BNM affects you.

Tobramycin BNM may cause dizziness, ringing in the ears, or light-headedness in some people. If you drink alcohol, your dizziness or light-headedness may be worse.

If you feel dizzy or light-headed after using Tobramycin BNM, do not drive.

Make sure you know how you react to Tobramycin BNM before you drive a car, operate machinery, use tools, or do anything else that could be dangerous if you are dizzy or light-headed.



If you are using tobramycin or another aminoglycoside antibiotic by injection, it may sometimes cause hearing loss, dizziness, kidney damage or may harm an unborn child.

In case of overdose

If you use too much

Immediately telephone your doctor, or the Poisons Information Centre telephone 0800 POISON or 0800 764 766; or go to Accident and Emergency at your nearest hospital, if you think that you or anyone else may have used too much Tobramycin BNM.

Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

Symptoms of an overdose may include dizziness, ringing in the ears, loss of balance, hearing problems, breathing problems, kidney problems, difficulty with nerve and muscle function.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are using Tobramycin BNM.

Like all medicines, Tobramycin BNM may occasionally cause side effects in some people. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Tobramycin BNM helps most people with cystic fibrosis but can cause side effects in a few people.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- runny, stuffy nose or nose bleed
- sneezing
- voice alteration with or without a sore throat
- difficulty swallowing (laryngitis)
- discolouration of the substance you cough up (sputum)
- decreased results for the tests of lung function
- weakness or muscle pain
- generally feeling unwell
- fever
- itching or itchy rash
- loss of your voice
- sore throat
- oral thrush, a fungal infection in the mouth which can be sore, creamy yellow, raised patches in the mouth



- diarrhoea
- nausea or vomiting
- heartburn
- disturbed sense of taste.

These side effects are usually mild.

Tell your doctor immediately if you notice any of the following:

- ringing in the ears or noises in the ears (such as hissing)
- hearing loss
- dizziness or light-headedness
- headache or drowsiness (feeling sleepy)
- clumsiness and lack of coordination
- chest pain or chest tightness
- increased coughing or coughing up blood
- increased wheezing or difficulty in breathing
- increased quantity of the substance you cough up (sputum)
- reduced appetite
- weight loss.

These may be serious side effects. You may need urgent medical attention. Serious side effects are rare.

Tell your doctor immediately, or go to Accident and Emergency at your nearest hospital if you notice any of the following:

- swelling of the face, lips, mouth, throat or tongue which may cause difficulty in swallowing or breathing
- shortness of breath
- skin rash
- unusual difficulty in breathing or talking with wheezing, coughing or chest tightness
- worsening of your underlying lung disease.

These are very serious side effects; you may need urgent medical attention or hospitalisation.

Tell your doctor or pharmacist if you notice anything else that is making you feel unwell.

Other side effects not listed above may also occur in some patients.

Do not be alarmed by this list of possible side effects.

You may not experience any of them.



After using Tobramycin BNM

Cleaning

Clean, disinfect and dry your nebuliser after each use, according to the manufacturer's instructions.

It may not work as well if it gets dirty.

Storage

Store Tobramycin BNM at 2 to 8°C in the refrigerator.

If you do not have a refrigerator available (for example, when you are transporting Tobramycin BNM), you can store the foil pouches (opened or unopened) at room temperature (up to 25°C) for up to 28 days.

Do not store any opened ampoules of Tobramycin BNM.

Once opened, the solution must be used immediately.

Do not store it or any other medicine in the bathroom, near a sink, or on a window sill. Do not leave it in the car on hot days.

Heat and damp can destroy some medicines.

Keep it and any other medicine where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Do not keep Tobramycin BNM past its expiry date.

Disposal

Return any unused medicine and any medicine past its expiry date (as shown on the labelling) to your pharmacy.

Medicines should not be disposed of in household waste. These measures will help to protect the environment.

Product description

What it looks like

Tobramycin BNM is a clear, slightly yellow solution. It is available in 5 ml single-use low density polyethylene (LPDE) ampoules packaged in an aluminium foil pouch.

Each carton of Tobramycin BNM contains 56 ampoules with 8 sealed foil pouches. Each foil pouch contains 7 ampoules.



Ingredients

Active ingredient:

- tobramycin

Inactive ingredients:

- sodium chloride
- sodium hydroxide*
- sulphuric acid*
- water for injections.

*These ingredients may have been added to adjust the pH of the final solution.

Tobramycin BNM does not contain preservatives, lactose, sucrose, gluten, tartrazine or any other azo dyes.

Sponsor details

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