

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about TOBI Solution for Inhalation ("TOBI").

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

The information in this leaflet was last updated on the date listed on the final page. More recent information on the medicine may be available.

You should ensure that you speak to your pharmacist or doctor to obtain the most up-to-date information on the medicine. You can also download the most up-to-date leaflet from: www.novartis.com.au (for Australia) or www.medsafe.govt.nz (for New Zealand). Those updates may contain important information about the medicine and its use of which you should be aware.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking TOBI against the benefits they expect it will have for you.

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

Keep this leaflet with the medicine.

You may need to read it again.

What TOBI is used for

TOBI 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 lung 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.

TOBI solution has been specially formulated for administration by inhalation via a nebuliser and compressor. When you inhale TOBI, the antibiotic can get straight into your lungs to fight against the infection and to improve your breathing.

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

Although TOBI does not cure your condition, it does help control it.

TOBI is not recommended for use in children younger than 6 years of age, as there have been no studies of its effects in this age group.

Ask your doctor if you have any questions about why TOBI has been prescribed for you. Your doctor may have prescribed TOBI for another reason.

TOBI is only available with a doctor's prescription. It is not addictive.

Before you use TOBI

When you must not use it

Do not use TOBI if you have an allergy to:

- TOBI 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.

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

Do not use TOBI:

- **after the expiry date printed on the pack has passed**
- **if the packaging is torn or shows signs of tampering**

In that case, return it to your pharmacist. If you use this medicine after the expiry date has passed, it may not work as well.

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

TOBI is not recommended for use in children under 6 years.

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

Before you start to use it

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

TOBI may affect your developing baby if you use it during pregnancy. Your doctor or pharmacist will discuss the possible risks and benefits of using TOBI 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 TOBI 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 if you have allergies to any other medicines or any other substances, such as 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 TOBI is right for you.

If you have not told your doctor about any of the above, tell them before you start using TOBI.

Taking other medicines

Tell your doctor 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.

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

- diuretics (fluid tablets), especially those that contain frusemide, or ethacrynic acid
- urea
- intravenous mannitol
- tobramycin or another aminoglycoside antibiotic by injection (e.g. amikacin, gentamicin, neomycin, streptomycin).

These medicines may be affected by TOBI, or may affect how well it works. You may need different amounts of your medicine, or you may need to take different medicines. Your doctor or pharmacist will advise you.

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

How to use TOBI

How much to use

Inhale TOBI only when prescribed by your doctor.

Do not exceed the recommended dose.

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

This is followed by 28 days of not taking TOBI. Repeat the 28 day on drug/28 day off drug cycle.

Follow all directions given to you by your doctor and pharmacist carefully.

They may differ from the information contained in this leaflet.

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

How to use it

TOBI solution is contained in a ready-to-use ampoule and is specifically formulated for inhalation therapy using a PARI LC PLUS reusable nebuliser and a De Vilbiss Pulmo-Aide®air compressor or PARI Pro-Neb System reusable nebuliser.

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

Breathe normally through the mouthpiece of the nebuliser until all of the TOBI 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 taking several different inhaled treatments and performing therapies for cystic fibrosis, you should use TOBI LAST.

Use TOBI at about the same time every day.

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

Inhale TOBI twice daily.

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

How to inhale TOBI

1. Wash your hands thoroughly with soap and water and fully dry hands.
2. Just before use, cut or tear open the foil pouch and remove one TOBI ampoule by gently pulling apart one of the attached ampoules at the bottom tabs.
3. Put the other ampoule(s) back in the foil pouch and keep it in the refrigerator.
4. Lay out all the pieces of your nebuliser on a clean, dry paper or cloth towel:
 - a. nebuliser top
 - b. nebuliser cup
 - c. inspiratory valve cap
 - d. mouthpiece with valve
 - e. tubing
5. Check that you have the suitable compressor, and tubing to connect the nebuliser and compressor.
6. Follow the appropriate instructions for use for your type of nebuliser. You must read the leaflet provided with the nebuliser by the manufacturer.
7. Check that your nebuliser and compressor are working properly according to the manufacturer's instructions before you start to take your medicine.
8. Remove the nebuliser top from the nebuliser cup by twisting the top anticlockwise and then lifting it.
9. Place the nebuliser top on the towel and stand the nebuliser cup upright on the towel.
10. 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.
11. Open the TOBI ampoule by holding the bottom tab with one hand and twisting off the top with your other hand.
12. Squeeze all the contents of the ampoule into the nebuliser cup.
13. Replace the nebuliser top (a), put the mouthpiece (d) and the inspiratory valve cap (c) in place on the nebuliser, and then connect the compressor as indicated in your nebuliser leaflet.
14. 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.
15. Sit or stand in an upright position so that you can breathe normally.
16. 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.
17. Continue until all of the TOBI solution is gone and there is no longer any mist being produced.

It should take about 10-15 minutes to inhale all of the treatment. You may hear a spluttering sound when the nebuliser cup is empty.

How long to use it

Use TOBI twice daily every day for 28 days, followed by a 28 day period off TOBI.

Continue using TOBI in these 28 day on/28 day off cycles for as long as your doctor or pharmacist tells you.

If you have any questions about how long to use TOBI, ask your doctor or pharmacist.

If you forget to use it

If there are at least 6 hours to your next dose, use TOBI 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 TOBI 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 you getting an unwanted side effect.

If you are not sure whether to skip the dose, talk to your doctor or pharmacist.

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

If you use too much (Overdose)

Immediately telephone your doctor or the Poisons Information Centre for advice or go to accident and emergency at your nearest hospital if you think that you or anyone else may have used too much TOBI.

The telephone numbers are:

- Australia: 13 11 26
- New Zealand: 0800 POISON or 0800 764 766

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

Signs 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.

While you are using TOBI

Things you must do

Keep TOBI in the foil pouch (opened or unopened) in the pack until it is time for your dose.

If you take the medication out of the pouch it will not keep well. TOBI is sensitive to very strong light.

Consult the package insert supplied with TOBI for detailed information and diagrams describing the correct use and care of your inhalation equipment and instructions on how to use TOBI.

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

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

Tell any other doctors, dentists, and pharmacists who are treating you that you are using TOBI.

If you are about to be started on any new medicine, tell your doctor, dentist or pharmacist that you are using TOBI.

If you plan to have surgery that needs a general anaesthetic, tell your doctor or dentist that you are using TOBI.

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 TOBI which you have stored at room temperature for more than 28 days.

Do not dilute or mix other medications, with TOBI in the nebuliser.

Never use a dirty or clogged nebuliser.

Do not share your nebuliser with other people.

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

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

Do not stop using TOBI, or lower 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 TOBI 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 TOBI affects you.

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

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

Make sure you know how you react to TOBI 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 taking tobramycin or another aminoglycoside antibiotic by injection, it may sometimes cause hearing loss, dizziness, and kidney damage, and may harm an unborn child.

Side effects

TOBI helps most people with cystic fibrosis, but can cause side effects in a few people.

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

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

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

You may not experience any of them.

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

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

- runny or stuffy nose
- 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
- muscle pain
- generally feeling unwell
- itching or itchy rash
- loss of your voice
- sore throat
- disturbed sense of taste.

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

- ringing in the ears
- hearing loss
- noises in the ears (such as hissing)
- dizziness
- light-headedness
- clumsiness and lack of co-ordination
- chest pain or chest tightness
- increased coughing, wheezing or difficulty in breathing
- generally feeling unwell
- discoloration of the substance you cough up (sputum).

These may be serious side effects of TOBI. 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, with wheezing or coughing or chest tightness
- worsening of your underlying lung disease

These are serious side effects. If you have them, you may have had a serious allergic reaction to TOBI. You may need urgent medical attention or hospitalisation.

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

Other side effects not listed may occur in some patients.

After using TOBI

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 TOBI between 2-8°C in the refrigerator.

If you do not have a refrigerator available (for example, when you are transporting TOBI), 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 TOBI.

Once opened, the solution should be used immediately.

Do not leave this medicine in the car on hot days or on window sills.

Heat and intense light can destroy some medicines.

Keep TOBI 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.

Disposal

If your doctor tells you to stop using TOBI or the solution has passed its expiry date, ask your pharmacist what to do with any that is left over.

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

Product description

What it looks like

Each carton of TOBI contains 56 single-dose ampoules (a 28-day supply). The ampoules are in 14 pouches, with 4 ampoules in each pouch.

TOBI is supplied in clear, plastic ampoules that are packaged in foil pouches. The solution is slightly yellow and may darken a little with age, but this does not affect the quality of the product (as long as it is stored within the recommended storage conditions).

Ingredients

Active ingredient:

Each 5 mL single dose ampoule contains tobramycin 300 mg.

Inactive ingredients:

- sodium chloride
- water for injections
- nitrogen
- sulphuric acid#
- sodium hydroxide#

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

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

Sponsor

TOBI solution for inhalation is supplied in

Australia by:

NOVARTIS Pharmaceuticals Australia Pty Limited
 ABN 18 004 244 160
 54 Waterloo Road
 North Ryde NSW 2113
 Telephone 1800 671 203

New Zealand by:

Novartis New Zealand Limited
 Private Bag 65904 Mairangi Bay Auckland
 Building G, 5 Orbit Drive Rosedale Auckland
 0632
 Telephone 0800 652 422

® = Registered Trademark

Australian Registration Number:

TOBI 300 mg/5 mL Solution for Inhalation
 AUST R 73172

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