Tobra-day® Injection

Consumer Medicine Information (CMI) summary

The full CMI on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why is Tobra-day being given?

Tobra-day contains the active ingredient tobramycin sulfate. Tobra-day is an antibiotic given to treat serious lung infections caused by bacteria in patients with cystic fibrosis. It works by killing the bacteria causing the infection.

For more information, see Section 1. Why is Tobra-day being given? in the full CMI.

2. What should I know before Tobra-day is given?

Do not use if you have ever had an allergic reaction to Tobra-day or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section 2. What should I know before Tobra-day is given? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Tobra-day and affect how it works.

A list of these medicines is in Section 3. What if I am taking other medicines? in the full CMI.

4. How is Tobra-day given?

Tobra-day is always given to you under the supervision of your doctor or healthcare professional. Your doctor will decide what dose and how long you will receive it for.

More instructions can be found in Section 4. How is Tobra-day given? in the full CMI.

5. What should I know while Tobra-day is being given?

Things you should do	• If you are about to be started on any new medicine, remind your doctor and pharmacist that you have been given Tobra-day. • Remind any doctor, dentist, pharmacist or nurse you visit that you have been given Tobra-day. • If you become pregnant while being given Tobra-day, tell your doctor immediately. • If you are going to have surgery, tell the surgeon or anaesthetist that you have been given this medicine. • Keep all your doctor's appointments so that your progress can be checked.
Driving or using machines	• Be careful driving or operating machinery after you have been given Tobra-day.
Looking after your medicine	• Tobra-day will be stored in the surgery, pharmacy or ward of a hospital, refrigerated between 2°C and 8°C but not frozen.

For more information, see Section 5. What should I know while Tobra-day is being given? in the full CMI.

6. Are there any side effects?

Tobra-day may cause headache, fever, chills, nausea, vomiting, loss of appetite and weakness, redness and swelling at the site of the injection, burning or creeping sensation of the skin, kidney problems, hearing loss, dizziness and vertigo, shortness of breath, wheezing or difficulty breathing, swelling of the face, lips, tongue or other parts of the body, rash, itching or hives on the skin.

For more information, including what to do if you have any side effects, see Section 6. Are there any side effects? in the full CMI.

Tobra-day® Injection *(toe-bruh-my-sin)*

Active ingredient: *tobramycin sulfate*

Consumer Medicine Information (CMI)

This leaflet provides important information about using Tobra-day. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about Tobra-day Injection being given.**

Where to find information in this leaflet:

1. Why is Tobra-day being given?

Tobra-day contains the active ingredient tobramycin sulfate. Tobra-day belongs to a group of medicines called aminoglycosides.

Tobra-day is an antibiotic used to treat serious lung infections caused by bacteria in patients with cystic fibrosis. It works by killing the bacteria causing the infection.

Follow all directions given to you by your doctor, nurse or pharmacist. They may differ from the information contained in this leaflet.

If you do not understand any instructions given to you by your doctor, nurse or pharmacist ask them for help.

Your doctor may have prescribed it for another reason. **Ask your doctor if you have any questions about why this medicine has been prescribed for you.**

2. What should I know before Tobra-day is given?

Warnings

Tobra-day should not be given to children under 5 years of age. There is not enough information to recommend the use of this medicine for children under the age of 5 years.

You should not be given Tobra-day if:

- you or your family members have a mitochondrial mutation disease (condition caused by variants in the genome of mitochondria, the parts of your cell which help make energy) or of loss of hearing due to antibiotic medicines; certain mitochondrial mutations may increase your risk of hearing loss with this product.
- you have had hearing loss or severe dizziness after being treated with tobramycin or other aminoglycosides.
- **the solution is discoloured, cloudy, turbid, or a precipitate is present. The injection is normally a clear colourless solution.** The solution is normally a clear straw coloured liquid.
- **it causes a precipitate, discolouration or cloudiness to form when added to an intravenous (IV) solution.**
- **the date is after the expiry date printed on the pack, or if the packaging is torn or shows signs of tampering.** The doctor or nurse will check to ensure the medicine is not past the expiry date and has not been tampered with.
- you are allergic to
  - any medicine containing tobramycin or tobramycin sulfate, or any of the ingredients listed at the end of this leaflet.
  - any other aminoglycoside antibiotic such as streptomycin, gentamicin, amikacin, kanamycin, netilmicin or neomycin.

Always check the ingredients to make sure you can use this medicine.

Check with your doctor if you:

- have allergies to any medicines, food, preservatives, or dyes.
- have or have had the following medical conditions:
  - a history of kidney problems including if these develop while being given Tobra-day
  - hearing loss
  - dizziness, spinning sensation or ringing in the ears
  - previous hearing loss or dizziness while being given Tobra-day
  - Parkinson's disease

- conditions causing muscle weakness such as myasthenia gravis.

- or your family members have a mitochondrial mutation disease (condition caused by variants in the genome of mitochondria, the parts of your cell which help make energy) or of loss of hearing due to antibiotic medicines; certain mitochondrial mutations may increase your risk of hearing loss with this product.

If you are not sure whether you should be given Tobra-day talk to your doctor.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section 6. Are there any side effects?

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed. Tobra-day passes into the breast milk and there is a possibility that the baby may be affected.

If you have not told your doctor about any of the above, tell them before you are given Tobra-day.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket, health food shop, herbalist or naturopath.

Some medicines may interfere with Tobra-day and affect how it works. These include but are not limited to:

- penicillin or other penicillin type antibiotics or cephalosporin
- medicines used to relax muscles
- pain killers
- cough and cold remedies
- alcohol
- heart or blood pressure medications.

You must not be given Tobra-day if you are taking:

- diuretics or fluid tablets such as frusemide or ethancynic acid
- antibiotics such as polymyxin B, colistin, cisplatin, vancomycin
- aminoglycoside antibiotics such as neomycin, streptomycin, gentamycin, amikacin, kanamycin or netilmicin
- antibiotics used to treat fungal infections such as amphotericin B
- ibuprofen, a medicine used to treat pain, fever and arthritis
- methoxyflurane a medicine used to reduce pain during medical procedures.

These medicines may be affected by Tobra-day or may affect how well Tobra-day works. You may need different amounts of your medicines, or you may need to take difference medicines.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Tobra-day.

4. How is Tobra-day given?

Tobra-day must only be given by a doctor or a healthcare professional.

How it is given

Tobra-day is used in a certain dose as a once a day injection. This once a day injection works just as well as giving a number of smaller doses throughout a day.
It should be diluted in a suitable solution and slowly infused into a vein over a period of 30 to 60 minutes.

How much is given

- Your doctor will decide what dose of Tobra-day you will receive and how long you will receive it for. This depends on your medical condition and other factors such as your weight.
- Tobra-day is given as a slow injection once a day.

If you are given too much Tobra-day

Overdose is unlikely to occur as Tobra-day is always given to you under the supervision of a doctor.

However, if you notice any symptoms of an overdose even weeks after being given Tobra-day, **you should immediately:**

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Symptoms of an overdose may include:

- drowsiness
- hearing loss
- dizziness, spinning sensation or ringing in the ear
- passing little or no urine
- difficulty breathing, breathlessness.

5. What should I know while Tobra-day is being given?

Things you should do

If you are about to be started on any new medicine, remind your doctor and pharmacist that you have been given Tobra-day.

Tell any other doctors, dentists, and pharmacists who treat you that you have been given Tobra-day.

If you are going to have surgery, tell the surgeon or anesthetist that you have been given this medicine.

Keep all your doctor's appointments so that your progress can be checked. Your doctor may do some tests from time to time to make sure this medicine is working and to prevent unwanted side effects.

Call your doctor straight away if you:

- become pregnant while being given Tobra-day.

Remind any doctor, dentist, pharmacist, or nurse you visit that you have been given Tobra-day.

If you feel light-headed, dizzy, or faint when getting out of bed or standing up, get up slowly.

Standing up slowly, especially when you get up from a bed or a chair, will help your body get used to the change in position and blood pressure. If this problem continues to get worse talk to your doctor.

Driving or using machines

Be careful driving or operating machinery after you have been given Tobra-day.

Tobra-day may cause dizziness or tiredness in some people. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.

Looking after your medicine

Tobra-day will

- be stored in the surgery, pharmacy, or ward of a hospital, refrigerated between 2°C and 8°C but not frozen.
- only be opened when it is time for you to have the injection.

It will be kept where young children cannot reach it.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

The risk of side effects increases if you

- have poor kidney function
- are elderly
- are on a long-term medical treatment
- have a serious medical condition.

Do not be alarmed by the following list of side effects. You may not experience any of them.

Less serious side effects

Less serious side effects	What to do
• nausea, vomiting, diarrhoea • nausea, loss of appetite and weakness • mild rash, itching • tiredness, muscle weakness • disorientation • numbness or weakness of arms and legs • headache, fever, chills • unusual bruising or bleeding under the skin • sore mouth, throat or mouth ulcer • looking pale, lack of energy • burning or creeping sensation of the skin • redness and swelling at the injection site • yellowing of the skin and eyes • swollen painful abdomen	**Speak to your doctor if you have any of these less serious side effects and they worry you.** **This list includes the more common side effects of your medicine.**

Serious side effects

Serious side effects	What to do
• kidney problems, e.g. increase or decrease in urination • ringing in the ears (known as tinnitus) • hearing loss • dizziness and vertigo	**Call your doctor straight away or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.**

Very serious side effects

Very serious side effects	What to do
• swelling of the face, lips, tongue or other parts of the body may be experienced. • rash, itching or hives on the skin • shortness of breath, wheezing or difficulty breathing These may be symptoms of an allergic reaction to tobramycin.	**Call your doctor straight away or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.** **These side effects are very rare.**

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

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side affects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

Tobra-day is a prescription medicine and is only administered under a doctor's supervision.

What Tobra-day contains

Active ingredient (main ingredient)	Tobramycin sulfate equivalent to 500 mg of tobramycin
Other ingredients (inactive ingredients)	Sulfuric acid Sodium hydroxide Water for injections

Do not take this medicine if you are allergic to any of these ingredients.

Tobra-day does not contain lactose, sucrose, gluten, tartrazine, alcohol, dyes or any preservatives.

What Tobra-day looks like

Tobra-day is a clear straw coloured solution in an amber glass vial with a rubber stopper and aluminum seal with plastic flip off cap.

It is supplied in a 7 mL vial with 5 mL of solution in packs of 10.

(AUST R 150481)

Who distributes Tobra-day

Tobra-day is made in Australia by:

Phebra Pty Ltd

19 Orion Road, Lane Cove West,

NSW 2066, Australia.

Telephone: 1800 720 020.

Tobra-day is distributed in New Zealand by:

AFT Pharmaceuticals Ltd

PO Box 33-203 Takapuna,

Auckland, New Zealand.

This leaflet was prepared in July 2022.