Tobra-day®

Contains 500 mg in 5 mL Tobramycin (as sulfate)
toe-bruh-MY-sin

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Tobra-day. It does not contain all the available information. It does not take the place of talking to your doctor.

All medicines have risks and benefits. Your doctor has weighed the risks of you being given Tobra-day against the benefits they expect it will have for you.

If you have any concerns about being given this medicine, ask your doctor.

Keep this leaflet in a safe place.
You may need to read it again.

What Tobra-day is used for

Tobra-day is an antibiotic used to treat serious lung infections caused by bacteria in patients with cystic fibrosis.

This medicine belongs to a group of medicines called aminoglycosides.

It works by killing the bacteria causing the infection.

Do not give this medicine 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.

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

This medicine is available only with a doctor's prescription.

Before you are given Tobra-day

When you must not be given the medicine

You should not be given Tobra-day if you have an allergy to:

- any medicine containing tobramycin or tobramycin sulfate
- any of the ingredients listed at the end of this leaflet
- any other aminoglycoside antibiotic such as streptomycin, gentamicin, amikacin, kanamycin, netilmicin or neomycin.

Some of the symptoms of an allergic reaction may include:

- 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.

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

- diuretics or fluid tablets such as frusemide or ethacrynic acid
- aminoglycoside antibiotics such as neomycin, streptomycin, gentamicin, amikacin, kanamycin or netilmicin
- antibiotics such as polymixin B, colistin, cisplatin, vancomycin
- 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.

You should not be given this medicine if you have had hearing loss or severe dizziness after being treated with tobramycin or other aminoglycosides.

You should not be given this medicine if the solution is discoloured, cloudy, turbid, or a precipitate or particles are present. The solution is normally a clear, straw to pale yellow coloured liquid.
You should not be given this medicine if it causes a precipitate, discolouration or cloudiness to form when added to an intravenous (IV) solution.

You should not be given this medicine 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.

If you are not sure whether you should be given this medicine talk to your doctor.

Before you are given it

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

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

- a history of kidney problems including if these developed 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.

Tell your doctor if you are pregnant or plan to become pregnant.
Your doctor can discuss with you the risks and benefits involved.

Tell your doctor if you are breastfeeding.
This medicine 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 him/her before you are given Tobra-day.

Taking other medicines

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

Some medicines may interfere with Tobra-day Injection. These include:

- penicillin or other penicillin type antibiotics or cephalosporin
- medicines used to relax muscles.

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

- diuretics or fluid tablets such as frusemide or ethacrynic acid
- antibiotics such as polymixin B, colistin, cisplatin, vancomycin
- aminoglycoside antibiotics such as neomycin, streptomycin, gentamicin, 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 it works. You may need different amounts of your medicine, or you may need to take different medicines.

Your doctor and pharmacist have more information on medicines to be careful with, or avoid, while being given Tobra-day.

How Tobra-day is given

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.
Tobra-day must only be given by a doctor or nurse or other suitably trained person.

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 your medicine you will receive and for how long you will receive it. 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 (overdose)

As Tobra-day is always given to you under the supervision of your doctor, it is unlikely you will receive an overdose.

However, if you notice any symptoms of an overdose, even weeks after being given Tobra-day, immediately contact your doctor or the Poisons Information Centre (telephone 13 11 26) for advice, or go to the Emergency Department at the nearest hospital. 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.

While you are being given Tobra-day

Things you must 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 this medicine.

If you are going to have surgery, tell the surgeon or anaesthetist that you have been given this medicine.
It may affect other medicines used during surgery.

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

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

Things to be careful of

Be careful driving or operating machinery until you know how Tobra-day affects you.
This medicine 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.

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 bed or chairs, will help your body get used to the change in position and blood pressure. If this problem continues or gets worse, talk to your doctor.

Side effects

Tell your doctor or nurse as soon as possible if you do not feel well while you are being given Tobra-day.
This medicine may have unwanted side effects in a few people. 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.

If you are over 65 years of age you may have an increased chance of getting side effects.

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

Ask your doctor to answer any questions you may have.

If any of the following happen tell your doctor immediately or go to the Emergency Department at your nearest hospital:

- rash, itching or hives on the skin
- swelling of the lips, tongue or other parts of the body
- shortness of breath, wheezing or trouble breathing.

These may be symptoms of an allergic reaction to tobramycin.

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

- kidney problems, e.g. increase or decrease in urination
- ringing in the ears (known as tinnitus)
- hearing loss
- dizziness and vertigo.

These are serious side effects of Tobra-day. You may need urgent medical attention.

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

- nausea, vomiting, diarrhoea
- mild rash, itching
- tiredness, muscle weakness
- disorientation
- numbness or weakness of arms and legs
- nausea, loss of appetite and weakness
- 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.

Tell your doctor or nurse if you notice anything that is making you feel unwell.
Other side effects not listed above may also occur in some people. If you notice any other effects check with your doctor.

Some side effects can only be found when your doctor does tests from time to time to check your progress.

After being given Tobra-day

Tell your doctor or nurse immediately if you notice any of the following side effects, even if they occur several weeks after stopping treatment with Tobra-day:

- kidney problems, e.g. increase or decrease in urination
- dizziness
- ringing in the ears (known as tinnitus)
- hearing loss
- vertigo.

Storage

Tobra-day will be stored in the surgery, pharmacy or ward of a hospital. The injection will be refrigerated between 2°C and 8°C but not frozen.

Tobra-day will only be opened when it is time for you to have the injection.

Product description

What it looks like

Tobra-day is a clear, straw to pale yellow solution in an amber glass vial with a rubber stopper and aluminium seal with plastic flip off cap in packs of 10.

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

Ingredients

Tobra-day contains tobramycin sulfate equivalent to 500 mg of tobramycin in 5 mL water for injections.

It may also contain sulfuric acid and sodium hydroxide for pH adjustment.

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

Manufacturer

Tobra-day is made in Australia by:
Phebra Pty Ltd
19 Orion Road,
Lane Cove West, NSW 2066,
Australia

Tobra-day is distributed in New Zealand by:
AFT Pharmaceuticals Ltd
PO Box 33-203 Takapuna,
Auckland,
New Zealand

Tobra-day tobramycin (as sulfate)
500 mg in 5 mL of solution in a 7 mL vial.
AUST R 150481

Phebra Product Code INJ093

This leaflet was amended in
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