

Tadim

Colistimethate sodium sterile powder for nebuliser solution

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Tadim. 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 taking Tadim against the benefits they expect it will have for you.

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

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

What Tadim is used for

Tadim contains the active ingredient colistimethate sodium, an antibiotic that fights infections caused by *Pseudomonas aeruginosa*.

This is a very common bacterium that infects the lungs of nearly all patients with cystic fibrosis at some time during their lives. If the infection is not properly controlled it will continue to damage the lungs, causing further problems.

Tadim is used to treat chest infections caused by *Pseudomonas aeruginosa* in people with cystic fibrosis. The medicine is breathed into the lungs (inhaled) via a nebuliser so that more of the antibiotic can work against the bacteria causing the infection.

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.

Before you use Tadim

When you must not use it

You should not use Tadim if you have an allergy to:

- any medicine containing colistimethate sodium

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 use this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If you take this medicine after the expiry date has passed, it may not work as well. The expiry date refers to the last day of the stated month.

If you are not sure whether you should use this medicine, talk to your doctor.

Before you use 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:

- kidney problems

- porphyria (a rare metabolic disease that some people are born with)
- asthma
- myasthenia gravis (a rare disease where your muscles are extremely weak and get tired very quickly).

You may need to take a lower dose of Tadim.

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 or planning to breast-feed.

The active ingredient in Tadim passes into breast milk and there is a possibility that your baby may be affected. Your doctor will discuss with you the risks and benefits of using Tadim if you are breastfeeding.

If you have not told your doctor about any of the above, tell them before you use Tadim.

Taking other medicines

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

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

- antibiotics such as **cephalothin sodium, gentamicin, amikacin and tobramycin**. Using Tadim at the same time as these other antibiotics could increase your risk of kidney problems.

- other medicines which can affect the kidneys, such as tacrolimus, ACE inhibitors, Angiotensin Receptor Blockers (ARBs), cyclosporin, Non-Steroidal Anti-inflammatory Drugs (NSAIDs) like aspirin.
- medicines which can affect the nerves (e.g. cocaine, methamphetamine, ketamine, or medicines for Parkinson’s disease).
- muscle relaxing medicines, which may be used as part of a general anaesthetic if you have an operation. Tadim can prolong the effect of such medicines. If you need to have a general anaesthetic, tell the anaesthetist that you are using Tadim.

If you suffer from myasthenia gravis and are also taking other antibiotics called macrolides (such as azithromycin, clarithromycin or erythromycin) or antibiotics called fluoroquinolones (such as ofloxacin, norfloxacin and ciprofloxacin), taking Tadim further increases the risk of muscle weakness and breathing difficulties.

Having colistimethate sodium as an infusion at the same time as receiving Tadim as an inhalation can increase your risk of side effects.

These medicines may be affected by Tadim or may affect how well it works. You may need different amounts of your medicines, or you may need to use different medicines.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

How to use Tadim

Follow all directions given to you by your doctor, pharmacist or nurse carefully.

They may differ from the information contained in this leaflet.

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

How much to use

The recommended dose for adults and children over the age of two years is **1-2 vials reconstituted and used with a nebuliser two or three times a day**. Your doctor will work out the best dose for you. This will depend on the seriousness of your infection, your general health and the type of nebuliser you will be using. Not all nebulisers are the same.

Always read the instructions for the nebuliser that you will use to inhale Tadim, as well as this leaflet.

Your doctor will work out the best dose for you.

Tadim may be reconstituted with Water for Injections (WFI) or a 50:50 mixture of WFI and 0.9% Sodium Chloride Injection. It is then inhaled using a nebuliser.

Check with the Pulmonary or Cystic Fibrosis Nurse to make sure you have the right nebuliser and compressor.

When to use it

You should use your **first dose** of Tadim when you are with your doctor or nurse.

Use Tadim after **physiotherapy** (if you have physiotherapy) and after using any **other nebulised medicines or bronchodilator** that you have been prescribed.

Tadim has to be breathed in from a nebuliser. It can be inhaled using any nebuliser system that can be used to deliver antibiotics to the lungs.

If you use Tadim with a conventional nebuliser you should make sure the room is well ventilated.

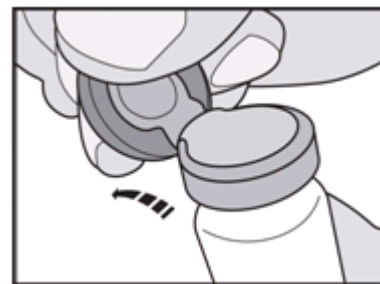
How to prepare Tadim

Your doctor or nurse will show you how to use Tadim with your nebuliser.

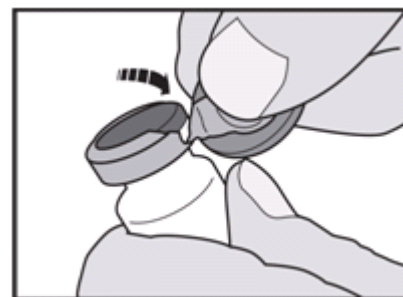
The following are general instructions on how to dissolve Tadim.



1. Flip open the Tadim plastic cap. Locate the lip on the plastic top, shown by the arrow marked “FLIP UP”. Using the thumb under the lip, push the plastic top up by about 40°.



2. Grasp the plastic top as shown and pull open slowly, like a hinge, to almost 180°.



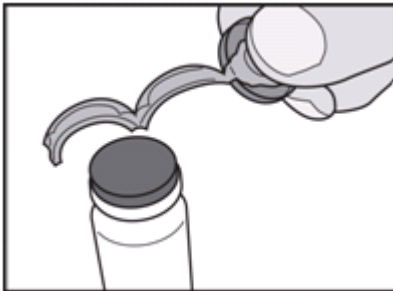
3. Pull the plastic top backwards so that the metal seal starts to tear open. During this step hold **both** the plastic and metal portion of the cap and slightly angle/twist the top (to either the left or the right) so that the metal collar is broken on **one side** only.



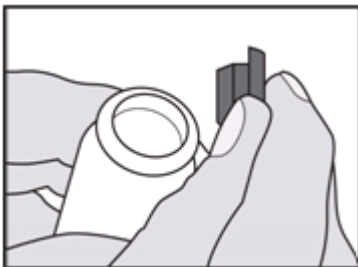
4. Once the seal is broken on **one side**, hold the vial tightly and push the cap backwards (holding both the plastic and metal portion of the cap) whilst rotating the vial in the opposite direction.



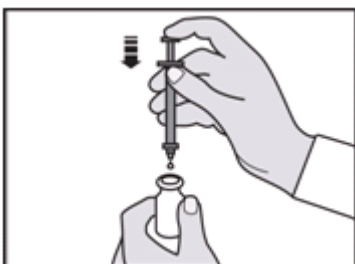
5. Continue opening the vial as described in step 4.



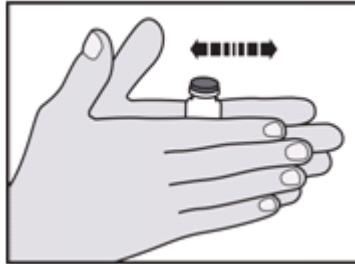
6. Remove the Flip Tear seal to reveal the vial stopper.



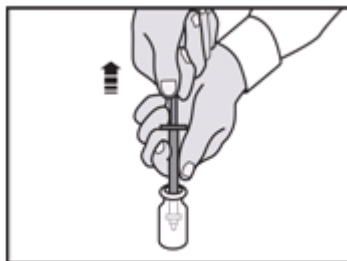
7. Remove the rubber stopper carefully.



8. Slowly add Water for Injections (WFI) or a 50:50 mixture of WFI and 0.9% Sodium Chloride Injection to the Tadim vial using a syringe. Note: a needle is not required. **(The nebulisation instructions provided by your doctor will tell you the correct volume of liquid to add to the Tadim vial.)**



9. Replace the rubber bung and roll the vial gently between both hands to dissolve the Tadim in the liquid. This should help pick up the powder 'settled' on the base & sides of the vial. You may need to leave the vials to stand for 5-10 minutes for the powder to fully dissolve. Avoid shaking the vial too hard. Vials that are shaken stay foamy for longer.



10. Remove the rubber bung and withdraw the Tadim solution from the vial with a syringe (a needle is not required). **(The nebulisation instructions provided by your doctor will tell you the correct volume of liquid to withdraw from the Tadim vial.)**



11. Add the appropriate volume of Tadim solution into the nebuliser.

Any unused solution from the vial or the nebuliser should be disposed of immediately after use. Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines you no longer require. These measures will help to protect the environment.

Once prepared, Tadim should be used immediately. Tadim contains no anti-microbial preservatives.

If it is not possible to use the solution immediately, store it in the refrigerator. Stored solutions **must not** be kept for **more than 24 hours** after you have prepared it.

There is a chance of serious lung side effects if the solution is used more than 24 hours after it was prepared.

Do not use solution from a vial on more than one occasion.

How long to use it for

Continue using the medicine for as long as your doctor tells you.

This medicine helps to treat your infection. It is important to keep using your medicine even if you feel well.

If you forget to use it

Inhale the dose as soon as you remember, unless it is near the time for your next dose. Do not have a double dose to make up for a forgotten dose.

If you use too much (overdose)

Immediately telephone your doctor, or go to the Emergency Department at the nearest hospital, if you think that you or anyone else may have used too much Tadim. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

Symptoms of an overdose may include:

- irregular breathing, breathlessness
- muscle weakness
- changes in sight
- spinning sensation
- sensation of burning or prickling of the skin of the face
- seeing things that are not there
- slurred speech
- confusion
- flushing (reddening of the face).

In Australia, contact the Poisons Information Centre on 13 11 26 for further advice on overdose management.

While you are using Tadim

Things you must do

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are using Tadim.

Tell any other doctors, dentists, and pharmacists who treat you that you are using this medicine.

If you are going to have surgery, tell the surgeon or 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.

Things to be careful of

Tadim may make you feel dizzy, confused or have problems with your sight, such as blurred vision.

If this happens to you, do not drive a car, use any tools or machines, or do anything else that could be dangerous.

Side effects

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

This medicine helps most people with a chest infection caused by *Pseudomonas aeruginosa* but it 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 attention if you get some of the 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.

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

- sore throat
- sore mouth.

Tell your doctor as soon as possible if you notice any of the following:

- cough
- tightness in the chest
- difficulty with breathing
- choking sensation

The above list includes the more common side effects of your medicine.

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

- allergic reactions

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.

These are serious side effects that may require medical attention.

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

Other side effects not listed above may also occur in some people. Some of these side effects (for example, changes in kidney function) can only be found when your doctor does tests from time to time to check your progress.

Ask your doctor or nurse if you do not understand anything in this list.

After using Tadim

Storage

Tadim vials should be stored below 25°C.

Tadim contains no preservatives. Once the solution is prepared, it should be used immediately and any remainder discarded.

If it is not possible to use the solution immediately, store it in a refrigerator. Stored solutions **must not** be kept for **more than 24 hours** after you have prepared it.

There is a chance of serious lung side effects if the solution is used more than 24 hours after it was prepared.

Do not use solution from a vial on more than one occasion.

Keep it 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

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines you no longer require. These measures will help to protect the environment.

Product description

What it looks like

Tadim is a sterile powder for nebuliser solution. It is supplied as a sterile white to off-white powder in a glass vial. It is supplied in packs containing 30 vials.

Ingredients

Each vial of Tadim contains 1 million International Units (IU) of colistimethate sodium, which weighs about 80 milligrams. There are no other ingredients.

Tadim contains no preservatives.

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

Supplier

Tadim is supplied by:

Phebra Pty Ltd
19 Orion Road,
Lane Cove West, NSW 2066,
Australia

AUST R 165709

This leaflet was amended in November 2022.

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