

PACKAGE LEAFLET: INFORMATION FOR THE USER

Tadim **1 million International Units (IU)** **Powder for Nebuliser Solution** colistimethate sodium

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, nurse, physiotherapist or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, nurse, physiotherapist or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Tadim is and what it is used for
2. What you need to know before you take Tadim
3. How to take Tadim
4. Possible side effects
5. How to store Tadim
6. Contents of the pack and other information

1. WHAT TADIM IS AND WHAT IT IS USED FOR

Tadim contains the active substance colistimethate sodium, and is given as an inhalation to treat chronic chest infections in patients with cystic fibrosis. Tadim is used when these infections are caused by specific bacteria called *Pseudomonas aeruginosa*.

This is a very common bacteria 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.

In order to administer Tadim, the powder contained in its vial should be dissolved with appropriate diluent solution, sterile saline (salt water) or sterile water and then breathed (inhaled) into the lungs using a suitable inhaler device so that more of the antibiotic can target the bacteria causing the infection.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE TADIM

In certain circumstances your doctor may decide not to prescribe Tadim.

Do not use Tadim if:

- you are **allergic** (hypersensitive) to colistimethate sodium, colistin or other polymyxins;
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If this applies to you, see your doctor before you start taking Tadim.

Warning and precautions with Tadim and tell your doctor if:

- you have or have had **kidney problems**;

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

If any of these apply to you, tell your doctor.

In premature and new-born babies, special care should be taken when using Tadim as the kidneys are not yet fully developed.

Other medicines and Tadim

Tell your doctor or pharmacist if you are taking or have recently taken or might take any other medicines **These medicines may interfere with the effect of Tadim.**

- medicines which can affect how your kidneys function. Taking such medicines at the same time as Tadim can increase the risk of damage to the kidneys.
- medicines which can affect your nervous system. Taking such medicines at the same time as Tadim can increase the risk of side effects in your nervous system.
- medicines called muscle relaxants, often used during general anaesthesia. Tadim can increase the effects of these medicines. If you have a general anaesthetic, let your anaesthetist know that you are having 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.

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice using this medicine.

There is no information about the safety of Tadim in pregnant women. Your doctor should advise you before using Tadim where benefits of the medicine exceed the risk.

Colistimetate sodium may be secreted in the breast milk. Please discuss the use of Tadim with your doctor..

Driving and using machines

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 or use any tools or machines.

3. HOW TO TAKE TADIM

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Tell your doctor if you have **problems with your kidneys** as you may need to take a lower dose of Tadim.

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

Take your Tadim **after physiotherapy** (if you have physiotherapy). This will ensure that your lungs are clear so that Tadim can work effectively. If you also take other inhaled medicines, your doctor will tell you which order to take them in.

The recommended dose for adults, adolescents and children aged 2 years or older is **1-2 vials** (1-2 million units) **two or three times a day** (maximum 6 million units per day).

The recommended dose for children less than 2 years old is half to 1 vial (0.5-1 million units) twice daily (maximum 2 million units per day).

Your doctor may decide to adjust the dose depending on your circumstances.

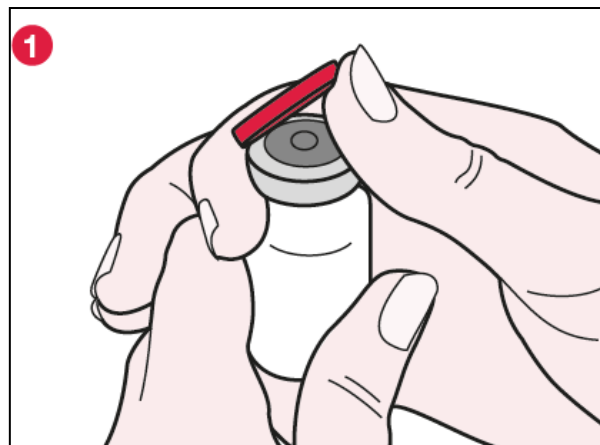
Tadim is inhaled from a device called a nebuliser. Tadim can be taken using any nebuliser system that can be used to deliver antibiotics to the lungs in the form of a mist. You should make sure the room is well ventilated.

How to prepare Tadim

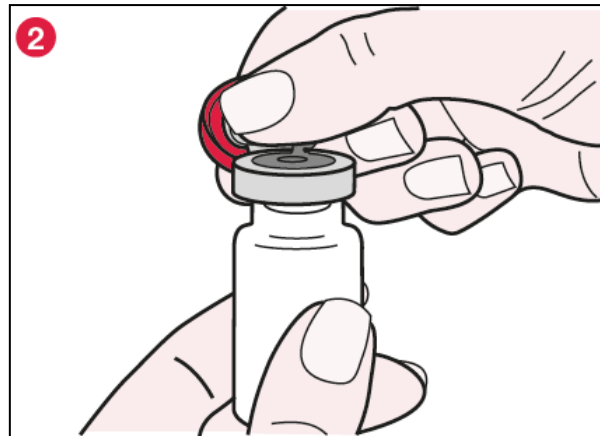
Your doctor or nurse will show you how to prepare and use Tadim with your nebuliser.

Before Tadim can be placed into the nebuliser and inhaled it must first be dissolved with **sterile water, sterile 0.9% saline** (salt water) or a **half and half mixture of sterile water and sterile 0.9% saline** (salt water) as directed below. **Your doctor or nurse will tell you the correct volume of liquid to add to each Tadim vial and how many Tadim vials you need to prepare and use for each dose with your nebuliser.**

- 1) Locate the lip on the red plastic top near the arrow marked “FLIP UP”. Then holding the vial in one hand and the plastic top with the other hand, **turn the top a small amount anti-clockwise**. Place a thumb under the lip and push the top up to about 90° (see diagram 1).



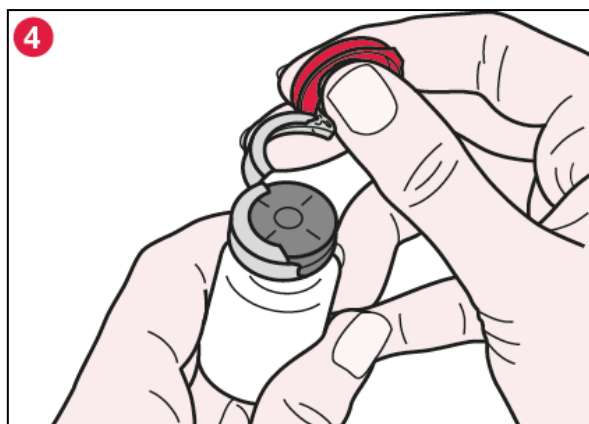
- 2) Grasp the plastic top as shown in diagram 2 and pull open slowly, like a hinge, to almost 180°.



- 3) Turn the vial around so that the plastic top is pointing towards you. Holding the centre of the top as shown, **pull it downwards and twist slightly to either the right (diagram 3a) or the left so that the metal seal is broken on one side only (diagram 3b).**

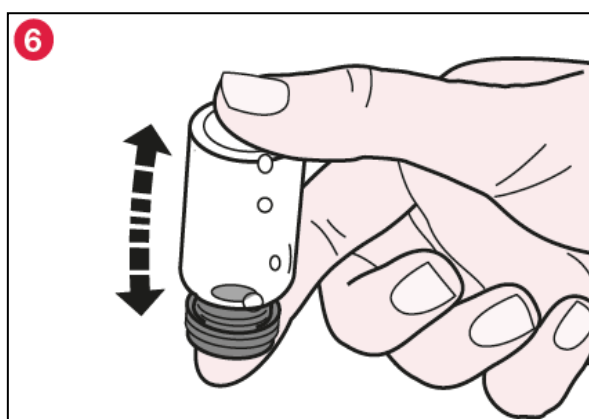


- 4) Once the seal is broken, hold the vial firmly and peel off the metal seal to reveal the whole of the rubber stopper (diagram 4).

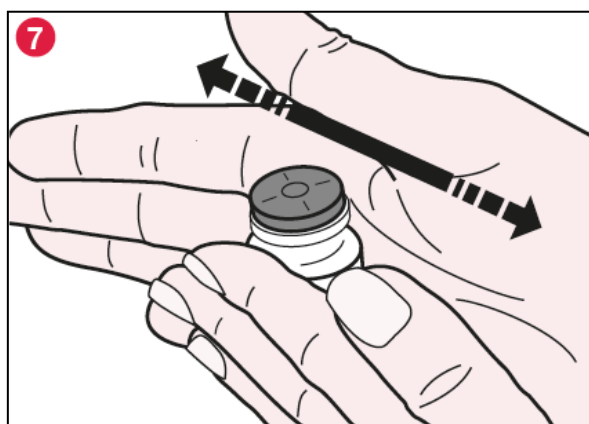


5) Remove the rubber stopper from the vial of Tadim by holding the outside edge of the stopper only and place it upside-down on a clean surface. Slowly add sterile water, sterile 0.9% saline, or sterile water and sterile 0.9% saline to the vial, **adding the volume of liquid your doctor or nurse has told you.**

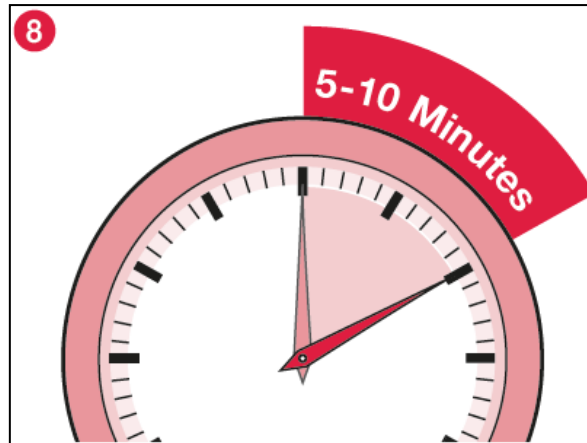
6) Replace the rubber stopper and gently turn the vial upside down twice (diagram 6).



7) Roll the vial gently between both hands to dissolve all the Tadim powder visible on the base and side of the vial (diagram 7). **Do not shake** the vial too hard as this may make the solution foam.



8) Once most of the powder is dissolved leave the vial to stand for 5-10 minutes to let any foam disappear and to allow any remaining powder to dissolve.



Pour the solution into the nebuliser and inhale immediately. If it is not possible to use the solution immediately replace the stopper in the vial and store for no longer than 24 hours in a refrigerator. **Do not use any solutions that have been prepared for more than 24 hours.** See section 5 'How to store Tadim' for instructions on how to store or dispose of any unused Tadim.

If you take more Tadim than you should

If you realise that you have taken more Tadim than your doctor has recommended (or if someone else has taken some of your Tadim), contact your doctor straight away.

The symptoms of taking too much Tadim can include:

- tingling or numbness around the lips and face
- dizziness and spinning sensation (vertigo)
- slurred speech
- visual disturbance
- confusion
- mental disturbance
- flushing (reddening of the face)

If you forget to take Tadim

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

If you stop taking Tadim

Do not stop your treatment early unless your doctor says that you can. Your doctor will tell you how long your treatment will last.

If you have any further questions on the use of this medicine ask your doctor or nurse.

4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Tadim can sometimes cause **allergic reactions** like **skin rash**. If this happens you should **stop taking Tadim** and tell your doctor immediately.

Breathing in Tadim through a nebuliser can make some people notice **tightness in their chest, feel wheezy, cough** or become **breathless** (sometimes described as choking sensation) . For this reason, the first dose should be taken when you are with your doctor or nurse. Your doctor may also advise you to take a medicine to help prevent any breathlessness. Your doctor may check your breathing at your clinic visits.

Tadim might also affect your **kidneys**, usually if the dose is high or you are taking other medicines that may affect your kidneys.

Tadim may sometimes cause you to have a **sore mouth** or **sore throat**.

Reporting of side effects

If you get any side effects talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system listed in Appendix V. By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE TADIM

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the vial and carton. The expiry date refers to the last day of that month.

Unopened Tadim vials do not require any special storage conditions.

Tadim contains no preservatives. Once prepared, Tadim solutions should preferably be used immediately. If this is not possible solutions should be stored for no longer than 24 hours in a refrigerator. **Do not use any solutions that have been prepared for more than 24 hours.**

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Tadim contains

The **active substance** is colistimethate sodium.

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

What Tadim looks like and contents of the pack

Tadim is a powder for nebuliser solution, supplied as a white to off-white powder in a glass vial.

Tadim is supplied in packs containing 30 vials.

Marketing Authorisation Holder

[To be completed nationally]

Manufacturer

Xellia Pharmaceuticals ApS
Dalslandsgade 11
DK- 2300, Copenhagen S
Denmark

This medicine is authorised in the Member States of the European Economic Area and in the United Kingdom (Northern Ireland) under the following names:

Austria, Netherlands, Sweden, France: Tadim

Germany, Denmark, Norway, United Kingdom (Northern Ireland), Italy, Spain, Portugal:
Promixin

This leaflet was last approved in 2026-03-19