PACKAGE LEAFLET: INFORMATION FOR THE USER

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

Read all of this leaflet carefully before you are given this medicine

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, nurse or pharmacist.
- If any of the side effects gets serious, or you notice any side effects not listed in this leaflet, please tell your doctor, nurse or pharmacist.

In this leaflet

1. WHAT TADIM IS AND WHAT IT IS USED FOR

Tadim contains colistimethate sodium. It is an **antibiotic** that is given by injection to treat some types of serious infections caused by certain bacteria.

Tadim is used when other antibiotics are not suitable.

2. WHAT YOU NEED TO KNOW BEFORE YOU ARE GIVEN TADIM

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

Do not have Tadim and tell your doctor if:
- you are allergic (hypersensitive) to colistimethate sodium, colistin or to other polymyxins.

If this applies to you, tell your doctor before you are given Tadim.

Warning and Precautions
Take special care with Tadim and tell your doctor, pharmacist or nurse 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).
- If you experience muscle spasm, fatigue or increased urine output at any time, tell your doctor immediately as these events may be related to a condition known as **pseudo-Bartter syndrome**.

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

Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including non-prescription medicines. **These medicines may interfere with the effects 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 anaesthetia. 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 Tadim as an infusion at the same time as receiving colistimethate sodium as an inhalation can increase your risk of side effects.

Pregnancy and breast-feeding
You may be given Tadim if you are pregnant or trying to get pregnant if your doctor considers the benefits are greater than the possible risks to your baby. It is unknown if having Tadim may harm your unborn baby.

It is not recommended that you breast-feed while you are taking this medicine as Tadim can pass into breast milk. A decision to discontinue/abstain from Tadim therapy must be taken by your doctor taking into account the benefit of breast-feeding for the child and the benefit of the therapy for the mother.

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.

Tadim contains sodium. This medicine contains less than 1 mmol sodium (23 mg) per vial, that is to say essentially ‘sodium-free’.

3. HOW YOU WILL BE GIVEN TADIM

Your treatment with Tadim will be given to you by your doctor as an infusion into a vein over 30 – 60 minutes.

The usual daily dose in adults is 9 international million units, divided into two or three doses. If you are quite unwell, you will be given a higher dose of 9 million international units once at the start of treatment.

In some cases, your doctor may decide to give a higher daily dose of up to 12 million international units.

The usual dose in children weighing up to 40 Kg is 75,000 to 150,000 international units per kilogram body weight, divided into three doses.
Higher doses have occasionally been given in cystic fibrosis.

Children and adults with kidney problems, including those on dialysis, are usually given lower doses. Your doctor will monitor your kidney function regularly while you receive Tadim.

If you are given too much Tadim
As a doctor or nurse will be giving you Tadim, it is unlikely that you will receive an incorrect dose. Tell your doctor or nurse if you have any concerns about the amount of medicine that you are given.
The symptoms of having too much Tadim can include:

- dizziness and spinning sensation (vertigo)
- slurred speech
- visual disturbance
- confusion
- mental disturbance
- flushing (reddening of the face)
- kidney problems
- muscle weakness
- feeling as though you cannot breathe

If you were not given Tadim when expected
If you think that you have missed a dose of Tadim and it is **less than 3 hours** since you should have been given the dose, tell your doctor or nurse.

If it is **more than 3 hours** after the missed dose the doctor or nurse will **wait for your next dose.**

Stopping Tadim
Your doctor will decide how long you should be given Tadim. It is important that your treatment is completed as advised by your doctor or your symptoms may get worse.

If you have any further questions on the use of this product, ask your doctor.

4. POSSIBLE SIDE EFFECTS

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

Tadim can sometimes cause **allergic reactions** like **skin rash** or red and lumpy skin rash, swollen eyelids, face, lips, mouth or tongue, itching, difficulty breathing or swallowing. If this happens, your Tadim treatment will be **stopped immediately**.

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

You may experience, after intravenous administration, the following symptoms that may be related to a condition known as **pseudo-Bartter syndrome** (see section 2):

- muscle spasm
- increase in urine output
- fatigue

Very common side effects (affecting more than 1 person in 10)
- blood tests may show changes in the way the kidneys are working
- headache
- tingling or numbness around the mouth, lips and face
- itching
- muscle weakness

Rare side effects (affecting less than 1 person in 1,000)
- kidney failure

Other side effects can include:
- dizziness
- difficulty in controlling movements
- soreness at the site of injection

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. 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 Tadim out of the sight and reach of children.

Do not use Tadim after the expiry date which is stated on the vial or 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 should be used immediately.

Your doctor or nurse will dispose of any unused medicine safely. These measures will help to protect the environment.

6. FURTHER 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 supplied as a powder in a glass vial. The powder must be made into a solution for infusion.
Tadim is supplied in packs containing 10 vials.

Marketing Authorisation Holder
[To be completed nationally]

Manufacturer
Xellia Pharmaceuticals ApS
Dalslandsgade 11

DK-2300
Copenhagen S
Denmark

This medicinal product is authorised in the Member States of the EEA under the following names:
Austria, The Netherlands, Sweden: Tadim
Germany, Denmark, Norway: Promixin

This leaflet was last revised in 2025-01-17