

AZACTAM[®]

Aztreonam (azz-TREE-oh-nam)

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about AZACTAM[®]. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking AZACTAM against the benefits that are expected. This leaflet does not contain everything about AZACTAM. Your doctor has been provided with full information and can answer any questions you may have. Follow your doctor's advice even if it differs from what is in this leaflet.

Please read this leaflet carefully and keep it in a safe place so you may refer to it later.

What AZACTAM is used for

AZACTAM is used for the treatment of serious infections caused by bacteria. AZACTAM may be used in the treatment of infections present in various parts of the body and sometimes AZACTAM is given with other antibiotics.

Your doctor may have prescribed AZACTAM for another use. Ask your doctor if you have any questions about why AZACTAM was prescribed for you.

How AZACTAM works

AZACTAM works by killing or preventing the growth of the bacteria that is causing your infection.

The use of AZACTAM to treat your condition can lead to side-effects, which are discussed below.

How AZACTAM is used

AZACTAM will be administered as an injection or infusion in a hospital or clinic. Your doctor or nurse will administer AZACTAM to you. AZACTAM may be used alone or with other medicines.

Before you receive AZACTAM

When you must not take AZACTAM:

- You must not take AZACTAM if you have a history of severe allergic reactions to AZACTAM or to any of the ingredients listed at the end of this leaflet.

Tell your doctor if you have allergies to:

- any other medicines, particularly antibiotics
- any other substances, such as foods, preservatives or dyes.

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

- You have diarrhoea or usually get diarrhoea when you take antibiotics or have ever suffered problems with your bowel. If you develop severe, prolonged or bloody diarrhoea during or after using AZACTAM. This side effect may be serious and require treatment. Do not treat with over-the-counter diarrhoea treatments, please consult your doctor.
- You have or have had liver disease
- You are pregnant or intend to become pregnant
- You are breast-feeding or plan to breast-feed
- You have renal (kidney) impairment

Taking other medicines

It is especially important to tell your doctor if you are taking any other medicines, including any that you buy without a prescription from your pharmacy, supermarket or health food shop. These medicines may be affected by AZACTAM or they may affect how well AZACTAM works.

Tell your doctor if you are taking any other medicines; especially if you are taking any of the following:

- Probenecid (medicine to treat gout)
- Frusemide (medicine that reduces fluid)

Know the medicines you take. Keep a list of your medicines with you to show your doctor or pharmacist.

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

While you are receiving AZACTAM

Things you must do:

- If you get severe diarrhoea tell your doctor or nurse immediately even if it occurs several weeks after AZACTAM has been stopped. Diarrhoea may mean that you have a serious condition affecting your bowel. You may need urgent medical care. Do not take any diarrhoea medicine without checking with your doctor first.
- You must tell your doctor immediately if you become pregnant during AZACTAM treatment
- Tell all of the doctors, dentists and pharmacists who are treating you that you are taking AZACTAM.
- If you are about to be started on any new medicine, tell your doctor and pharmacist that you are taking AZACTAM.

How to take AZACTAM

The dose of AZACTAM will be determined by your doctor; your doctor will consider the severity and location of your infection, your size and your medical history.

The dose of AZACTAM can range from 1.5g to 8g each day. This dose is given over 2, 3 or 4 injections throughout a 24-

hour period. AZACTAM will be injected directly into your vein over 3-5 minutes or it will be administered as an infusion over 30 minutes. AZACTAM can also be administered as an injection into a large muscle, such as the buttocks or thigh.

The AZACTAM injection will be prepared and administered by your doctor or nurse. You will not administer AZACTAM yourself.

If too much is given (overdose)

As your dose of AZACTAM will be determined and administered by a doctor, the chance of receiving an overdose is most unlikely. However, if an overdose should be given your doctor will give the appropriate treatment.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking AZACTAM.

Like all medicines, it is possible that AZACTAM may have unwanted side effects in some people. During treatment with AZACTAM you will require close medical supervision.

The more common side effects of AZACTAM are:

- Allergic reaction, itchy skin, flushing
- Rash, red/purple spots under the surface of the skin (bleeding under the skin), dermatitis

- Changes in blood cell counts and liver function tests (these will be monitored by your doctor)
- Diarrhoea, nausea, vomiting, abdominal cramps/bloating, mouth ulcer, altered taste
- Soreness at the injection site

Tell your doctor if you notice any of the following -

- Oral thrush - white, furry, sore tongue and mouth
- Vaginal thrush - sore and itchy vagina and/or discharge, itching or burning while passing urine
- Swelling, pain or inflammation at the site of the injection
- Any change to your bowel habits - diarrhoea or constipation, pain in the gut, indigestion or upset stomach
- Skin rash or itchiness, skin redness
- confusion, impairment of consciousness, epilepsy (fits or seizures), movement disorders; particularly in patients with renal (kidney) impairment and in association with beta-lactam antibiotic overdose.

Tell your doctor immediately, or go to accident and emergency at your nearest hospital if you notice any of the following:

- Signs of allergic reaction, such as swelling of the face, lips, tongue and/or throat with difficulty in swallowing or breathing.

- Severe and sudden onset of pinkish, itchy swellings
- Severe, persistent or bloody diarrhoea (which may be associated with stomach pain or fever). This is a rare side effect which may occur after treatment with antibiotics and can be a sign of serious bowel inflammation.

These are serious side effects. You may need urgent medical attention or hospitalisation.

After treatment with AZACTAM is finished.

Tell your doctor immediately if you notice any of the following side effects, particularly if they occur several weeks after the treatment with AZACTAM has stopped -

- severe abdominal cramps or stomach cramps
- watery and severe diarrhoea, which may also be bloody
- fever with one or both of the above symptoms

Although these side effects are rare, you may have a serious condition affecting your bowel and may need urgent medical attention. Do not take medicine to treat diarrhoea without first checking with your doctor.

Other side effects not listed above may also occur in some patients. Tell your doctor if you notice anything else that is making you feel unwell.

Product Description

AZACTAM for is a white powder that is prepared a solution intended for injection by your doctor or nurse.

Ingredients

Active Ingredient: Aztreonam

Inactive Ingredients: L-arginine

Storage

AZACTAM will be stored in the hospital or pharmacy under the appropriate conditions.

Sponsored by

Bristol-Myers Squibb Australia Pty Ltd,

4 Nexus Court, Mulgrave,

Victoria 3170, Australia

Registration Numbers:

AZACTAM 1g vial (pack of 10 vials) (AUST R 14032)

Where to get further information

Your doctor is the best person to answer any further questions you may have about AZACTAM. Anything your doctor tells

you about AZACTAM should be followed even if it is different from what is in this leaflet.

Date of Preparation: February 2019

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