

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using AZACTAM?

AZACTAM contains the active ingredient aztreonam. AZACTAM is used to treat serious infections caused by bacteria.

For more information, see Section [1. Why am I using AZACTAM?](#) in the full CMI.

2. What should I know before I use AZACTAM?

Do not use if you have ever had an allergic reaction to AZACTAM or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions or allergies, take any other medicines, if you have diarrhoea or usually get diarrhoea when you take antibiotics or have ever suffered problems with your bowel, or if you are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I use AZACTAM?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with AZACTAM and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use AZACTAM?

- The dose of AZACTAM will be determined by your doctor.
- AZACTAM will be administered as an injection or infusion in a hospital or clinic.

More instructions can be found in Section [4. How do I use AZACTAM?](#) in the full CMI.

5. What should I know while using AZACTAM?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are using AZACTAM.• Call your doctor straight away if you get severe, prolonged or bloody diarrhoea, even if it is several weeks after AZACTAM has stopped.
Things you should not do	<ul style="list-style-type: none">• Do not take any diarrhoea medicine without checking with your doctor first
Driving or using machines	<ul style="list-style-type: none">• Be careful before you drive or use any machines or tools until you know how AZACTAM affects you.
Drinking alcohol	<ul style="list-style-type: none">• Tell your doctor if you drink alcohol.
Looking after your medicine	<ul style="list-style-type: none">• AZACTAM will be stored in the hospital or pharmacy.

For more information, see Section [5. What should I know while using AZACTAM?](#) in the full CMI.

6. Are there any side effects?

Serious side effects include signs of an allergic reaction; swelling of the face, lips, tongue and/or throat with difficulty in swallowing or breathing; severe and sudden onset of pinkish, itchy swelling; blistering on the skin; ulcers in the eyes or mouth; severe persistent or bloody diarrhoea; flu-like symptoms or fever. Other side effects include itchy skin; flushing; rash; changes to bowel habits including diarrhoea, constipation, pain in the gut, indigestion or upset stomach; oral or vaginal thrush; swelling or pain at the injection site; confusion; impaired consciousness; fits or seizures; movement disorders; bleeding under the skin; dermatitis; nausea; vomiting; bloating; altered taste.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

AZACTAM[®] (Ay-ZAC-TAM)

Active ingredient(s): Aztreonam (azz-TREE-oh-nam)

Consumer Medicine Information (CMI)

This leaflet provides important information about using AZACTAM. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using AZACTAM.**

Where to find information in this leaflet:

1. [Why am I using AZACTAM?](#)
2. [What should I know before I use AZACTAM?](#)
3. [What if I am taking other medicines?](#)
4. [How am I given AZACTAM?](#)
5. [What should I know while using AZACTAM?](#)
6. [Are there any side effects?](#)
7. [Product details](#)

1. Why am I using AZACTAM?

AZACTAM contains the active ingredient aztreonam.

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.

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

2. What should I know before I use AZACTAM?

Warnings

Do not use AZACTAM if:

- you have a severe allergic reaction to AZACTAM, or any of the ingredients listed at the end of this leaflet.

Always check the ingredients to make sure you can use this medicine.

Check with your doctor if you:

- have allergies to:
 - any other medicines, particularly antibiotics
 - any of the substances, such as foods, preservatives or dyes.
- have or have had any other 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 have renal (kidney) impairment.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

- Check with your doctor if you are pregnant or intend to become pregnant.
- Check with your doctor if you are breastfeeding or intend to breastfeed.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements 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.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect AZACTAM.

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

4. How am I given AZACTAM?

How AZACTAM is given

- AZACTAM will be administered as an injection or infusion in a hospital or clinic.
- The AZACTAM injection will be prepared and administered by your doctor or nurse. You will not administer AZACTAM yourself.
- 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.

How much to take

- 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.

When to take AZACTAM

- AZACTAM is given over 2, 3 or 4 injections throughout a 24-hour period.

If you miss a dose of AZACTAM

- AZACTAM is administered in a hospital or clinic by a doctor or nurse. If you believe you have missed a dose inform your doctor or nurse straight away.

If you are given to much

- 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.

5. What should I know while using AZACTAM?

Things you should do

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

Call your doctor straight away if you:

- 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.

- become pregnant during AZACTAM treatment

Things you should not do

- Do not take any diarrhoea medicine without checking with your doctor first.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how AZACTAM affects you.

Drinking alcohol

Tell your doctor if you drink alcohol.

Looking after your medicine

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

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Serious side effects

Serious side effects	What to do
<p>Allergic Reaction</p> <ul style="list-style-type: none"> • Signs of allergic reaction, such as swelling of the face, lips, tongue and/or throat with difficulty in swallowing or breathing. <p>Skin</p> <ul style="list-style-type: none"> • Severe and sudden onset of pinkish, itchy swellings • blistering of the skin usually on the trunk or genital areas <p>Eyes and Mouth</p> <ul style="list-style-type: none"> • ulcers in the eyes or mouth <p>Gut and Digestive System</p> <ul style="list-style-type: none"> • 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. <p>General</p> <ul style="list-style-type: none"> • fever, generally feeling unwell, flu-like symptoms 	<p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p>

Other side effects

Less serious side effects	What to do
<p>Skin</p> <ul style="list-style-type: none"> • Skin rash or itchiness, skin redness <p>Gut and Digestive System</p> <ul style="list-style-type: none"> • Any change to your bowel habits - diarrhoea or constipation, pain in the gut, indigestion or upset stomach <p>Mouth</p>	<p>Tell your doctor if you have any of these side effects.</p>

<p>Less serious side effects</p> <ul style="list-style-type: none"> Oral thrush - white, furry, sore tongue and mouth <p>Injection Site</p> <ul style="list-style-type: none"> Swelling, pain or inflammation at the site of the injection <p>Genitals</p> <ul style="list-style-type: none"> Vaginal thrush - sore and itchy vagina and/or discharge, itching or burning while passing urine <p>Brain and Nervous System</p> <ul style="list-style-type: none"> 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. 	<p>What to do</p>
<p>Common side effects</p> <p>Skin</p> <ul style="list-style-type: none"> Allergic reaction, itchy skin, flushing Rash, red/purple spots under the surface of the skin (bleeding under the skin), dermatitis <p>Blood and Liver</p> <ul style="list-style-type: none"> Changes in blood cell counts and liver function tests (these will be monitored by your doctor) <p>Gut and Digestive System</p> <ul style="list-style-type: none"> Diarrhoea, nausea, vomiting, abdominal cramps/bloating <p>Mouth</p> <ul style="list-style-type: none"> Mouth ulcer, altered taste <p>Injection Site</p> <ul style="list-style-type: none"> Soreness at the injection site 	<p>What to do</p> <p>Speak to your doctor if you have any of these side effects and they worry you.</p>

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

During treatment with AZACTAM you will require close medical supervision.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

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

What AZACTAM contains

Active ingredient (main ingredient)	Aztreonam
Other ingredients (inactive ingredients)	L-arginine

Do not take this medicine if you are allergic to any of these ingredients.

What AZACTAM looks like

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

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

Who distributes AZACTAM

Bristol-Myers Squibb Australia Pty Ltd

4 Nexus Court, Mulgrave,

Victoria 3170, Australia.

Toll free number: 1800 067 567

Email: MedInfo.Australia@bms.com

AZACTAM is a registered trademark of Bristol-Myers Squibb Company.

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