

AUSTRAPEN®

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 AUSTRAPEN?

AUSTRAPEN contains the active ingredient ampicillin (as sodium). AUSTRAPEN is used to treat infections in different parts of the body caused by bacteria.

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

2. What should I know before I use AUSTRAPEN?

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

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

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

3. What if I am taking other medicines?

Some medicines may interfere with AUSTRAPEN 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 AUSTRAPEN?

AUSTRAPEN must only be given by a doctor or nurse.

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

5. What should I know while using AUSTRAPEN?

Things you should do

- Remind any doctor, dentist or pharmacist you visit that you are using AUSTRAPEN.
- If you develop itching with swelling or skin rash or difficulty breathing after you have been given

	<p>AUSTRAPEN, contact your doctor immediately.</p> <ul style="list-style-type: none"> ● If you get severe diarrhoea tell your doctor or pharmacist immediately. Do this even if it occurs several weeks after AUSTRAPEN has been stopped.
Driving or using machines	<ul style="list-style-type: none"> ● Be careful driving or operating machinery until you know how AUSTRAPEN affects you.
Looking after AUSTRAPEN	<ul style="list-style-type: none"> ● AUSTRAPEN is stored in the pharmacy or on the ward. ● AUSTRAPEN is kept in a cool dry place, protected from light, where the temperature stays below 25°C.

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

6. Are there any side effects?

Tell your doctor if you notice any of the following: pain or redness at the site of injection, oral thrush - white, furry, sore tongue and mouth, vaginal thrush - sore and itchy vagina and/or discharge, a mild rash.

Tell your doctor immediately or go to Emergency Department at your nearest hospital if you notice any of the following: a severe skin reaction, including severe rash or blisters, wheezing, irregular heart beat, feeling faint.

Tell your doctor immediately if you notice any of the following side effects, particularly if they occur several weeks after finishing treatment with AUSTRAPEN: severe abdominal cramps or stomach cramps, fever or watery and severe diarrhoea, which may also be bloody.

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.

AUSTRAPEN®

Active ingredient: *ampicillin (as sodium)*

Consumer Medicine Information (CMI)

This leaflet provides important information about using AUSTRAPEN. **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 AUSTRAPEN.**

Where to find information in this leaflet:

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

1. Why am I using AUSTRAPEN?

AUSTRAPEN contains the active ingredient ampicillin (as sodium). AUSTRAPEN is an antibiotic that belongs to a group of medicines called penicillins. These antibiotics work by killing the bacteria that are causing your infection.

AUSTRAPEN is an antibiotic used to treat infections in different parts of the body caused by bacteria.

AUSTRAPEN will not work against infections caused by viruses, such as colds or the flu.

Your doctor may have prescribed AUSTRAPEN for another reason. Ask your doctor why AUSTRAPEN has been prescribed for you.

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

There is no evidence that AUSTRAPEN is addictive.

2. What should I know before I use AUSTRAPEN?

Warnings

Do not use AUSTRAPEN if:

- you are allergic to ampicillin (as sodium), penicillins, cephalosporins or any of the ingredients listed at the end of this leaflet. Some of the symptoms of an allergic reaction may include:
 - skin rash
 - itching
 - difficulty breathing

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

If you are not sure whether you should be given AUSTRAPEN, talk to your doctor.

Check with your doctor if you:

- **have an allergy to AUSTRAPEN or any other penicillin.**
- **have any type of allergic reaction to cephalosporin medicines.**

You may have an increased chance of being allergic to AUSTRAPEN if you are allergic to cephalosporins.

- have any allergies to any other medicines or any other substances, such as foods, preservatives or dyes. This may include medicines that you buy without a prescription from your pharmacy, supermarket or health food shop.
- you have or have ever had any other health problems/ medical conditions, including asthma, kidney or liver disease.

If you have not told your doctor about any of the above, tell them before you are given AUSTRAPEN.

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.

Your doctor will discuss the risks and benefits of using AUSTRAPEN during pregnancy.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

Your doctor will discuss the risks and benefits of using AUSTRAPEN when breast-feeding.

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.

Some medicines may interfere with AUSTRAPEN. These include:

- allopurinol or probenecid for conditions such as gout
- some antibiotics e.g. tetracyclines, gentamicin, erythromycin and chloramphenicol.
- methotrexate

These medicines may be affected by AUSTRAPEN, or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines. Your doctor or pharmacist has more information on medicines to be careful with or avoid whilst receiving AUSTRAPEN.

Some antibiotics may decrease the effectiveness of some birth control pills.

Talk to your doctor about the need for an additional method of contraception whilst receiving AUSTRAPEN.

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

4. How do I use AUSTRAPEN?

How AUSTRAPEN is given

AUSTRAPEN may be given in two ways:

- as a slow injection into a vein
- as a deep injection into a large muscle, a joint or the sac surrounding the lung.

AUSTRAPEN must only be given by a doctor or nurse.

Your doctor will decide what dose and for how long you will receive AUSTRAPEN. This depends on your infection and other factors, such as your weight. For most infections, AUSTRAPEN is usually given in divided doses throughout the day.

To reduce microbial contamination, each AUSTRAPEN vial is used only once. Any remaining contents must be discarded.

If you have too much AUSTRAPEN

This rarely happens as AUSTRAPEN is administered under the care of a doctor. However, if you are given too much AUSTRAPEN, you may experience some of the side effects listed under Section 6 'Are there

any side effects?'. Your doctor has information on how to recognise and treat an overdose. Ask your doctor if you have any concerns. A very large overdose of AUSTRAPEN can cause brain upsets including fits.

If you think that you have been given too much AUSTRAPEN, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (Australia telephone 13 11 26) for advice, or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using AUSTRAPEN?

Things you should do

- If the symptoms of your infection do not improve within a few days, or if they become worse, tell your doctor.
- **If you develop itching with swelling or skin rash or difficulty breathing after you have been given AUSTRAPEN, contact your doctor immediately.**
- **If you get severe diarrhoea tell your doctor or pharmacist immediately. Do this even if it occurs several weeks after AUSTRAPEN 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 first checking with your doctor.**
- An illness consisting of a rash, swollen glands, joint pains and fever may occur about a week after the treatment.
- If you get a sore white mouth or tongue after you have been given AUSTRAPEN, tell your doctor.
- Tell your doctor if you get vaginal itching or discharge. This may mean you have a fungal infection called thrush. Sometimes the use of AUSTRAPEN allows fungi to grow and the above symptoms to occur. AUSTRAPEN does not work against fungi.
- If you become pregnant while you are receiving AUSTRAPEN, tell your doctor.
- If you have to have any tests tell your doctor you have been given AUSTRAPEN. AUSTRAPEN may affect the results of some tests.
- Tell any doctor, dentist or pharmacist who is treating you that you have been given AUSTRAPEN.

Driving or using machines

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

AUSTRAPEN generally does not cause any problems with your ability to drive a car or operate machinery. However, as with many other medicines, AUSTRAPEN

may cause dizziness, drowsiness or tiredness in some people.

Looking after AUSTRAPEN

AUSTRAPEN will be stored in the pharmacy or on the ward. The medicine is stored in a cool dry place, protected from light, where the temperature stays below 25°C. AUSTRAPEN is not to be given after the expiry date on the label.

- **Do not use AUSTRAPEN if:**
- **the packaging is torn or shows signs of tampering**
- **the expiry date on the pack has passed. If AUSTRAPEN is given after the expiry date, it may have no effect at all, or worse, an unexpected effect.**

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.

Check with your doctor as soon as possible if you have any problems whilst receiving AUSTRAPEN, even if you do not think the problems are connected with the medicine or are not listed in this leaflet.

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

Less serious side effects

Less serious side effects	What to do
<ul style="list-style-type: none">• pain or redness at the site of injection• oral thrush - white, furry, sore tongue and mouth• vaginal thrush - sore and itchy vagina and/or discharge• a mild rash	Tell your doctor if you notice any of the following.

Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none">• a severe skin reaction, including severe rash, raised lumps, blisters or skin peeling; fever, flu-like feeling, body aches; shortness of breath; chest pain• wheezing• irregular heart beat• feeling faint, dizziness, feeling tired or weak• bruising	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.

Serious side effects	What to do
<ul style="list-style-type: none"> ● yellowing of your skin or eyes, light coloured stool, dark urine, unexplained persistent nausea, stomach problems, loss of appetite or unusual tiredness ● aches and pains <p>If you are suffering from glandular fever or some other more serious blood complaints, it is very common to develop a rash if you are given AUSTRAPEN. The rash will disappear after the AUSTRAPEN is stopped.</p>	

After finishing AUSTRAPEN

Serious side effects	What to do
<ul style="list-style-type: none"> ● severe abdominal cramps or stomach cramps ● watery and severe diarrhoea, which may also be bloody 	<p>Tell your doctor immediately if you notice any of the following side effects, particularly if they occur several weeks after</p>

Serious side effects	What to do
<ul style="list-style-type: none"> • fever, in combination with one or both of the above <p>These are rare but serious side effects. AUSTRAPEN can change bacteria (which are normally present in the bowel and normally harmless) to multiply and therefore cause the above symptoms. You may need urgent medical attention.</p>	<p>finishing treatment with AUSTRAPEN.</p>

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

This is not a complete list of all possible side effects. Other side effects not listed above may also occur in some patients. These include very rare cases of brain, blood and kidney disease.

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 AUSTRAPEN contains

Active ingredient (main ingredient)	Ampicillin (as sodium) 1000 mg
Other ingredients (inactive ingredients)	None
Potential allergens	N/A

Do not take this medicine if you are allergic to the above ingredient.

What AUSTRAPEN looks like

AUSTRAPEN is a white to almost white powder which has to be dissolved in water before it is injected (AUST R 29354).

Available in packs of 5 x 1000 mg vials.

Who distributes AUSTRAPEN

Alphapharm Pty Ltd trading as Viatris

Level 1, 30 The Bond

30-34 Hickson Road

Millers Point NSW 2000

www.viatris.com.au

Phone: 1800 274 276

This leaflet was prepared in May 2024.

AUSTRAPEN® is a Viatris company trade mark

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