

Cubicin®

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 being given Cubicin?

Cubicin contains the active ingredient daptomycin. Cubicin is used in adults and children (1 to 17 years of age) to treat complicated infections of the skin and the tissues under the skin.

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

2. What should I know before I am given Cubicin?

Do not use if you have ever had an allergic reaction to Cubicin 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 am given Cubicin?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Cubicin 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 is Cubicin given?

Cubicin will be given to you by a doctor or a nurse as it needs to be given as an injection or infusion into a vein.

- For adults, the dose will depend on how much you weigh and the type of infection being treated.
- For children (1 to 17 years of age), the dose will depend on the age of the patient, how much the child weighs, and the type of infection being treated.

More instructions can be found in Section [4. How is Cubicin given?](#) in the full CMI.

5. What should I know while being given Cubicin?

Things you should do

- If the symptoms of your infection do not improve, or if they become worse, tell your doctor.

	<ul style="list-style-type: none"> ● If you develop itching with swelling or skin rash or difficulty breathing while you are being given Cubicin tell your doctor immediately.
Things you should not do	<ul style="list-style-type: none"> ● Do not stop receiving Cubicin because you are feeling better, unless advised by your doctor. ● If you do not complete the full course prescribed by your doctor, all of the bacteria causing your infection may not be killed. These bacteria may continue to grow and multiply so that your infection may not clear completely or it may return.
Driving or using machines	<ul style="list-style-type: none"> ● Be careful driving or operating machinery until you know how Cubicin affects you
Looking after your medicine	<ul style="list-style-type: none"> ● It is unlikely you will have to store Cubicin powder at home.

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

6. Are there any side effects?

Like all medicines, Cubicin can cause side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

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.

Cubicin[®] (pronounced Q-bi-sin)

Active ingredient: *daptomycin* (pronounced DAP-toe-MY-sin)

Consumer Medicine Information (CMI)

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

Where to find information in this leaflet:

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

1. Why am I being given Cubicin?

Cubicin contains the active ingredient daptomycin. Cubicin is an antibiotic that belongs to a group of medicines called cyclic lipopeptides. These antibiotics work by killing the Gram-positive bacteria that are causing your infection.

Cubicin is used in adults and children (1 to 17 years of age) to treat complicated infections of the skin and the tissues under the skin.

It is also used in adults and children to treat blood infections. It is also used in adults to treat infections of the tissues that line the inside of the heart (including heart valves) – that are caused by *Staphylococcus aureus* bacteria.

Cubicin will not work against pneumonia (a serious infection or inflammation in the lung tissue).

Ask your doctor if you have any questions about why Cubicin has been prescribed for you.

Your doctor may have prescribed it for another purpose.

2. What should I know before I am given Cubicin?

Warnings

Do not use Cubicin if:

- you are allergic to daptomycin, the active ingredient, or any of the other ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body; rash, itching or hives on the skin.

Check with your doctor if you:

- have allergies to any other medicines, foods, dyes or preservatives
- have or have had any kidney problems. Your doctor may need to change the dose of Cubicin
- are suffering from diarrhoea
- are pregnant, or intend to become pregnant
- are breastfeeding or plan to breastfeed

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.

Like most medicines, Cubicin is not recommended in pregnancy. Your doctor will discuss with you the risks and benefits of having Cubicin during pregnancy.

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

You should not breast-feed your child during your treatment with Cubicin.

Children

Cubicin should not be administered to children below the age of 1 year due to possible side effects on muscles and nerves that were observed in animal studies.

Addiction

Cubicin is not addictive.

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 Cubicin and affect how it works.

Tell your doctor if you are taking:

- Warfarin (a medicine used to prevent blood clots).
- Statins or fibrates (medicines used to lower cholesterol)
- Cyclosporin (a medicine used to help prevent organ transplant rejection or to treat certain problems with the immune system)
- Non-steroidal anti-inflammatory drugs (NSAIDs) or COX-2 inhibitors, e.g. celecoxib (medicines used to relieve pain, swelling or other symptoms of inflammation)

- Tobramycin, another antibiotic used to treat various types of bacterial infections.

These medicines may be affected by Cubicin, or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

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

4. How is Cubicin given?

How it is given

Cubicin will be given to you by a doctor or a nurse as it needs to be given as an injection or infusion into a vein. For adults, the dose will depend on how much you weigh and the type of infection being treated.

For children (1 to 17 years of age), the dose will depend on the age of the patient, how much the child weighs, and the type of infection being treated.

Your doctor will decide on the dose and how long you will receive Cubicin.

If you have kidney problems, you may receive Cubicin less often, e.g. every other day. If you are receiving dialysis, and your next dose of Cubicin is due on a dialysis day, you will usually be given Cubicin after the dialysis session.

How Cubicin is given

- **Adults:** Cubicin is given directly into your blood stream by intravenous injection over about 2 minutes or by infusion (drip) over about 30 minutes.
- **Children (7-17 years of age):** Cubicin is given directly into the blood stream by infusion (drip) over 30 minutes.
- **Children (1-6 years of age):** Cubicin is given directly into your blood stream by infusion (drip) over 60 minutes.

If you are given too much Cubicin

Since Cubicin is usually given to you in hospital under the supervision of your doctor, it is very unlikely that you will be given too much of the medicine. Your doctor, nurse or pharmacist will be monitoring your progress and checking the medicine that you are given.

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

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**), 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 being given Cubicin?

Things you should do

If the symptoms of your infection do not improve, or if they become worse, tell your doctor.

If you develop itching with swelling or skin rash or difficulty breathing while you are being given Cubicin tell your doctor immediately.

You should tell your doctor that you are being treated with Cubicin if you are about to have a blood clotting test or any other blood tests. It may interfere with the results of some tests.

If you are going to have surgery, tell the surgeon or anaesthetist that you are being given Cubicin. It may affect other medicines used during surgery.

Call your doctor straight away if you have:

- **Tender or aching muscles or muscle weakness.**

Your doctor will make sure that you have a blood test and will decide whether or not you should continue Cubicin treatment. The symptoms generally go away within a few days of stopping Cubicin.

- **Any unusual tingling or numbness of the hands or feet, loss of feeling or difficulties in moving.**

Your doctor will decide whether or not you should continue treatment.

- **Diarrhoea, especially if you notice blood.**

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.

- **New or worsening fever, cough or difficulty breathing.**

These may be the signs of a rare, but serious lung disorder called eosinophilic pneumonia. If you experience these symptoms, tell your doctor. Your doctor will check the condition of your lungs and will decide whether or not you should continue Cubicin treatment.

Your doctor will perform blood tests to monitor the health of your muscles both before you start treatment and frequently during the course of treatment with Cubicin.

Your doctor will monitor your kidney function and the health of your muscles more frequently during Cubicin treatment if you have kidney problems.

Remind any doctor, dentist or pharmacist you visit that you are being given Cubicin.

Fungal Infections

If you get a sore white mouth or tongue while you are being given Cubicin or soon after stopping it, tell your doctor. Also tell your doctor if you get vaginal itching or discharge.

This may mean you have a fungal infection called thrush. Sometimes the use of Cubicin allows fungi to grow and the above symptoms to occur. Cubicin does not work against fungi.

Diarrhoea

Tell your doctor immediately if you develop diarrhoea, especially bloody diarrhoea, after your treatment has stopped.

Diarrhoea is a common problem that happens when taking antibiotics. It usually stops when the antibiotic is stopped.

Other medicines of the same class as Cubicin may also cause diarrhoea.

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

Things you should not do

- Do not stop receiving Cubicin because you are feeling better, unless advised by your doctor.
- If you do not complete the full course prescribed by your doctor, all of the bacteria causing your infection may not be killed. These bacteria may continue to grow and multiply so that your infection may not clear completely or it may return.

Driving or using machines

Be careful driving or operating machinery until you know how Cubicin affects you.

Cubicin generally does not cause any problems with your ability to drive a car or operate machinery. However, as with many other medicines, Cubicin may cause dizziness or tiredness in some people

Looking after your medicine

It is unlikely you will have to store Cubicin powder at home.

If you do have to store it:

- Keep it in a refrigerator (2°C to 8°C).
- Keep the vial in the outer carton in order to protect it from light.
- Do not store it or any other medicine in the bathroom or near a sink.
- Do not leave it in the car or on a window sill.

Heat and dampness can destroy some medicines.

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

Cubicin helps most people with certain infections, but it may have unwanted side-effects in a few people.

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.

Less serious side effects

Less serious side effects	What to do
<p>Difficulty thinking, working, or carrying out your usual daily activities because of:</p> <ul style="list-style-type: none">• headache• eye irritation• difficulty in sleeping (insomnia)• dizziness• spinning sensation (vertigo) <p>Behavioural changes such as:</p>	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>

Less serious side effects	What to do
<ul style="list-style-type: none"> ● anxiety <p>Infections:</p> <ul style="list-style-type: none"> ● oral thrush (symptoms include a white, furry, sore tongue and mouth) ● vaginal thrush (symptoms include sore and itchy vagina and/or discharge) ● inflammation and irritation of the vagina (vaginitis) ● fungal infections ● urinary tract infection <p>Stomach and bowels:</p> <ul style="list-style-type: none"> ● mild stomach upsets such as indigestion (dyspepsia), feeling sick (nausea), being sick (vomiting) or stomach pain ● abdominal pain, swelling or bloating ● flatulence 	

Less serious side effects	What to do
<ul style="list-style-type: none"> ● constipation or mild diarrhoea ● decreased appetite <p>Skin:</p> <ul style="list-style-type: none"> ● pain, itchiness or redness at the site of administration <p>Blood pressure problems such as:</p> <ul style="list-style-type: none"> ● high or low blood pressure <p>Other changes such as:</p> <ul style="list-style-type: none"> ● trembling ● taste disturbance ● flushes ● general pain, weakness or tiredness (fatigue) ● pain in the arms or legs, or joint pain 	

Serious side effects

Serious side effects	What to do
<p>Severe allergic reaction that may include:</p> <ul style="list-style-type: none">● anaphylaxis, a sudden life-threatening allergic reaction with the symptoms: sudden signs of allergy such as rash, itching or hives on the skin, swelling of the face, lips, tongue or other parts of the body, shortness of breath, wheezing or trouble breathing● difficulty breathing, new or worsening cough, new or worsening fever (these may be the signs of a rare, but serious lung disorder called eosinophilic pneumonia)● hypersensitivity reactions (serious allergic reactions) such as:<ul style="list-style-type: none">○ pus filled bumps that can spread over the	<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>

Serious side effects	What to do
<p>body, sometimes with a fever</p> <ul style="list-style-type: none"> ○ shivering or chills ○ flushed appearance ○ blistering rash (vesiculobullous rash, Stevens Johnson Syndrome/Toxic Epidermal Necrolysis) ○ swelling of the face, neck and throat ○ fainting ○ cough <p>Hypersensitivity reactions (serious allergic reactions including anaphylaxis, angioedema, drug rash with eosinophilia and systemic symptoms (DRESS) and pulmonary eosinophilia); and a serious lung disorder called eosinophilic pneumonia have been reported in patients given Cubicin.</p> <p>Movement changes such as:</p>	

Serious side effects	What to do
<ul style="list-style-type: none"> ● unexplained muscle pain, tenderness, weakness or cramps ● tingling, burning or numbness of arms and hands or legs and feet (paraesthesia) ● loss or difficulty moving the arms and/or legs 	

Serious side effects	What to do
<p>Heart related:</p> <ul style="list-style-type: none"> ● changes in heart rhythm <p>Liver related:</p> <ul style="list-style-type: none"> ● yellowing of the skin and eyes (jaundice) <p>Kidney related:</p> <ul style="list-style-type: none"> ● kidney problems, including kidney failure <p>Stomach and bowel related:</p> <ul style="list-style-type: none"> ● diarrhoea, especially bloody diarrhoea <p>Other changes such as:</p>	<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>

Serious side effects	What to do
<ul style="list-style-type: none"> • fainting • unusual bleeding in the skin and bruising 	

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

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 Cubicin contains

Active ingredient (main ingredient)	daptomycin 350 mg or 500 mg
Other ingredients (inactive ingredients)	sodium hydroxide

Cubicin does not contain preservatives or bacteriostatic agents.

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

What Cubicin looks like

Cubicin comes in a 10 mL glass vial containing a pale yellow to light brown powder.

Cubicin comes in two strengths:

Cubicin 350 mg vial (AUST R 143574)

Cubicin 500 mg vial (AUST R 143586)

Who distributes Cubicin

Merck Sharp & Dohme (Australia) Pty Limited

Level 1, Building A, 26 Talavera Road

Macquarie Park, NSW 2113 Australia

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