

Cubicin[®] (pronounced Q-bi-sin)

Powder for solution for injection

daptomycin (pronounced DAP-toe-MY-sin)

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Cubicin. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

The information in this leaflet was last updated on the date listed on the final page. More recent information on the medicine may be available.

You should ensure that you speak to your pharmacist or doctor to obtain the most up to date information on the medicine. You can also download the most up to date leaflet from

www.medsafe.govt.nz. Those updates may contain important information about the medicine and its use of which you should be aware.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking this medicine against the benefits they expect it will provide.

If you have any concerns about this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine. You may need to read it again.

What Cubicin is and what it is used for

What Cubicin is

The active substance in Cubicin is daptomycin. Cubicin is a powder for solution for injection or infusion.

Daptomycin is a cyclic lipopeptide natural product. It is an antibacterial that can stop the growth of certain bacteria called Gram-positive bacteria.

What it is used for

Cubicin is an antibiotic used in adults to treat:

- complicated infections of the skin and the tissues under the skin
- blood infections or 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 infections that cause pneumonia (a serious infection or inflammation in the lung tissue).

How Cubicin works

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.

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.

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

Cubicin is not addictive.

Before you are given Cubicin

When you must not have it

You must not have Cubicin if you are allergic (hypersensitive) to daptomycin, the active ingredient, or to 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.

You must not have this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

In that case, it should be returned to your pharmacist.

Before you are given it

This medicine is not to be given to a child under the age of 18 years.

There is not enough information to recommend the use of this medicine for children under the age of 18 years.

Tell your doctor if you:

- are allergic 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

Like most medicines, Cubicin is not recommended in pregnancy. Your doctor will discuss with you

the risks and benefits of having Cubicin during pregnancy.

- are breastfeeding or plan to breastfeed

Your doctor will discuss with you the risks and benefits involved.

Take special care with Cubicin

- If you have, or have previously had kidney problems. Your doctor may need to change the dose of Cubicin (see section 3 of this leaflet).
- If you suffer from diarrhoea.

If either of these applies to you, tell your doctor or nurse before you are given Cubicin.

Tell your doctor straight away if you develop any of the following symptoms:

- Serious, acute allergic reactions have been observed in patients treated with nearly all antibacterial agents, including Cubicin. Tell a doctor or a nurse straight away if you experience symptoms suggestive of allergic reaction, such as wheezing, difficulty breathing, swelling of the face, neck and throat, rashes and hives, fever (see section 4 of this leaflet for more information).
- Tender or aching muscles or muscle weakness (see section 4 of this leaflet for more information). If this happens, tell your doctor. He/she will make sure you have a blood test and will decide whether or not you should continue Cubicin treatment.
- Any unusual tingling or numbness of the hands or feet, loss of feeling or difficulties in moving. If this happens, tell your doctor who will decide whether or not you should continue treatment.
- Diarrhoea, especially if you notice blood.
- 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.

You should tell your doctor that you are being treated with Cubicin if you are about to have a blood clotting test, because Cubicin may interfere with the test result.

Cubicin is not used for the treatment of pneumonia (an infection or inflammation in the lung tissue).

Taking other medicines

Tell your doctor or pharmacist if you are taking, or have recently taken, any other medicines, including medicines obtained without a prescription.

Some medicines and Cubicin may interfere with each other.

It is particularly important that you mention the following:

- Statins, lipid-lowering agents used to lower cholesterol. It is possible that the risk of side effects affecting the muscles and blood values of a CPK (creatine phosphokinase) test may be higher when statins (which may affect muscles) are also taken during treatment with Cubicin. Your doctor may decide not to give you Cubicin or to stop the statins for a while.
- Tobramycin, an antibacterial agent used to treat various types of bacterial infections.
- Warfarin, an agent that prevents blood from clotting.
- 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)

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. Your doctor and pharmacist have more information.

If you have not told your doctor about any of these things, tell him/her before you are given this medicine.

Older people

If you are over 65 years of age, you will be given the same dose as other adults, provided your kidneys are working well.

Children and adolescents

The use of Cubicin to treat infections in children under 18 years of age has not been studied and is, therefore, not recommended.

Pregnancy and breast-feeding

- Cubicin is not usually given to pregnant women. Tell your doctor if you are pregnant, think you may be pregnant, or are planning to become pregnant.
- You should not breast-feed your child during your treatment with Cubicin. Before being given Cubicin, tell your doctor or nurse if you are breast-feeding.

Driving and using machines

Cubicin has no known effects on the ability to drive or use machines.

How Cubicin is given

Your medicine 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.

How much is given

Your doctor will decide what dose and how long you will receive Cubicin. The dose will depend on how much you weigh and the type of infection being treated. The usual adult dose for skin infections is 4 mg once daily for every kilogram (kg) of body weight; for blood or heart infections, it is 6 mg once daily for every kg of body weight.

How it is given

This dose is administered directly into your blood stream (into a vein) by injection over a period of about 2 minutes or by infusion over a period of about 30 minutes.

When it is given

Your doctor will determine when you are given Cubicin.

How long it is given for

A course of treatment usually lasts 1 to 2 weeks for skin infections, and 2 to 6 weeks for blood or heart infections. Your doctor will decide how long you should be treated.

If your kidneys do not work well, you may receive Cubicin less often, e.g. once 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.

If you are over 65 years of age, you will be given the same dose as other adults, provided your kidneys are working well.

If you miss a dose

If you think that you have missed a dose of treatment, tell a doctor or nurse or pharmacist at once.

Since Cubicin is given by a doctor or nurse, once a day, it is very unlikely that you will miss a dose.

If you are given too much (overdose)

Immediately telephone your doctor, or the National Poisons

Information Centre (telephone 0800 POISON or 0800764766), or go to Accident and Emergency at your nearest hospital, if you think that you may have been given too much Cubicin. Do this even if there are no signs of discomfort or poisoning.

Since Cubicin is given by a doctor or nurse, once a day, 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.

While you are being given Cubicin

Things you must 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 contact your doctor immediately.

Tell your doctor immediately if you develop any of the following symptoms:

- **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.

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.

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 become pregnant while taking this medicine, tell your doctor immediately.

If you are going to have surgery, tell the surgeon or anaesthetist that you are taking Cubicin.

It may affect other medicines used during surgery.

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking Cubicin.

Tell any other doctors, dentists, and pharmacists who treat you that you are taking Cubicin.

Things you must 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.

Do not give this medicine to anyone else, even if their condition seems similar to yours.

Do not use it to treat any other complaints unless your doctor tells you to.

Things to be careful of

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.

Side effects

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

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

All medicines can have 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.

Do not be alarmed by the following list of side effects. You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

Some side effects could be serious

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. These conditions need immediate medical attention. Tell your doctor or nurse straight away if you experience any of the following symptoms after receiving Cubicin:

- Chest pain or tightness
- Wheezing
- Difficulty breathing
- New or worsening cough
- New or worsening fever
- Flushed appearance
- Rashes and hives
- Swelling of the face, neck and throat
- Fainting

Tell your doctor straight away if you experience unexplained muscle pain, tenderness or weakness. Muscle problems can be serious; muscle breakdown (rhabdomyolysis) can result in kidney damage.

Some side effects are common

These side effects may affect between 1 and 10 in every 100 patients.

- Fungal infections
- Urinary tract infections
- Decreased number of red blood cells (anaemia)
- Anxiety
- Difficulty in sleeping (insomnia)
- Dizziness
- Headache
- High or low blood pressure
- Abdominal pain
- Constipation
- Diarrhoea
- Nausea
- Vomiting
- Flatulence
- Abdominal swelling or bloating
- Skin rash or itching
- Pain in arms or legs
- Pain, itchiness or redness at the site of infusion
- Fever
- Weakness

Some side effects are uncommon

These side effects may affect between 1 and 10 in every 1,000 patients.

- Blood disorders e.g. increased number of small blood particles called platelets (thrombocytosis), higher levels of certain types of white blood cells (eosinophilia).
- Decreased appetite
- Tingling or numbness of the hands or feet (paraesthesia)
- Taste disturbance
- Trembling
- Spinning sensation (vertigo)
- Irregular heart beat
- Flushes
- Indigestion (dyspepsia)
- Hives
- Joint pain
- Muscle pain
- Muscle weakness
- Kidney function disorders, including kidney failure
- Inflammation and irritation of the vagina (vaginitis)
- Shivering
- Tiredness (fatigue)

Some side effects are rare

These side effects may affect between 1 and 10 in every 10,000 patients.

- Yellowing of the skin and eyes (jaundice)

Numbness, tingling, and/or burning sensations in the arms and/or legs (peripheral neuropathy), blistering rash (vesicubullous rash) and cough have been also observed.

If any of these mentioned side effects affects you severely, tell your doctor or nurse.

Some people may have other side effects not yet known or mentioned in this leaflet.

After you are given Cubicin

Each Cubicin vial is to be used for one injection or infusion only. Any unused portion remaining in the vial should be discarded.

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.

Storage

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

If you do have to store it:

- Do not use after the expiry date shown on the box.
- Store original packages in a refrigerator at 2-8°C; avoid excessive heat. Keep it in a refrigerator (2°C to 8°C).

Keep out of the reach and sight of children.

Product description

What it looks like

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

Ingredients

Each vial contains daptomycin 350 mg or 500 mg as the active ingredient.

It also contains the following inactive ingredient:

- sodium hydroxide

Cubicin does not contain preservatives or bacteriostatic agents.

Sponsor

Cubicin is supplied in New Zealand by:

Novartis New Zealand Limited
Private Bag 65904
Mairangi Bay
Auckland

Building G, 5 Orbit Drive
Rosedale
Auckland 0632
Telephone 0800 652 422

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