

# Daptomycin Lupin

## 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 Daptomycin Lupin?

Daptomycin Lupin contains the active ingredient daptomycin. Daptomycin Lupin is used to treat complicated infections of the skin and the tissues under the skin. It is also used to treat blood infections and to treat infections of the tissues that line the inside of the heart. For more information, see Section [1. Why am I using Daptomycin Lupin?](#) in the full CMI.

### 2. What should I know before I use Daptomycin Lupin?

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

### 3. What if I am taking other medicines?

Some medicines may interfere with Daptomycin Lupin 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 Daptomycin Lupin?

- Your doctor will decide the dosage of Daptomycin Lupin that you will receive, depending on your condition.
- Daptomycin Lupin is given as an injection or infusion into a vein by your doctor in the hospital.

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

### 5. What should I know while using Daptomycin Lupin?

<b>Things you should do</b>	<ul style="list-style-type: none"><li>• Tell your doctor if: your infection is not improving or is getting worse; you have tender or aching muscles or muscle weakness; you have any unusual tingling or numbness of the hands or feet, loss of feeling or difficulties in moving; you have diarrhoea, especially if you notice blood; you have new or worsening fever, cough or difficulty breathing; you get a sore white mouth/tongue and vaginal itching or discharge.</li><li>• Tell your doctor if you are about to have a blood clotting test or any other blood tests.</li></ul>
<b>Things you should not do</b>	<ul style="list-style-type: none"><li>• Do not stop receiving this medicine if you are feeling better, unless advised by your doctor.</li><li>• If you do not complete the full course, all of the bacteria causing your infection may not be killed.</li></ul>
<b>Driving or using machines</b>	<ul style="list-style-type: none"><li>• Daptomycin Lupin may cause dizziness or tiredness in some people. Make sure you know how you react to Daptomycin Lupin before you drive a car, operate machinery, or do anything else that could be dangerous.</li></ul>
<b>Looking after your medicine</b>	<ul style="list-style-type: none"><li>• Daptomycin Lupin will be stored refrigerated in the pharmacy or on the hospital ward.</li></ul>

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

### 6. Are there any side effects?

Common side effects include oral thrush, vaginal thrush, inflammation and irritation of the vagina, fungal infections, pain, itchiness or redness at the site of administration, general pain, weakness or fatigue, trembling, decreased appetite, dizziness, spinning sensation, headaches, flushes, indigestion, nausea, abdominal pain, swelling, bloating, flatulence, constipation, mild diarrhoea, taste disturbance, eye irritation, insomnia, pain the arms or legs, or joints, anxiety, urinary tract infection and high or low blood pressure. Serious side effects in particular that need to be noted are anaphylaxis, difficulty breathing or worsening cough and fever, unexplained muscle pain, tenderness, weakness or cramps, tingling, burning or numbness of arms and hands or legs and feet, loss or difficulty in moving arms/legs, changes in heart rhythm, jaundice, kidney problems or failure, diarrhoea

or bloody diarrhoea, fainting, unusual bleeding in the skin and bruising and hypersensitivity reactions (serious allergic reactions). 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.

# Daptomycin Lupin

Active ingredient(s): *daptomycin*

## Consumer Medicine Information (CMI)

This leaflet provides important information about using Daptomycin Lupin. **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 Daptomycin Lupin.**

Where to find information in this leaflet:

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

## 1. Why am I using Daptomycin Lupin?

**Daptomycin Lupin contains the active ingredient daptomycin.** Daptomycin Lupin is an antibiotic that belongs to a group of medicines called cyclic lipopeptides.

**Daptomycin Lupin is used to kill gram-positive bacteria that cause infections.**

In adults and children (1 to 17 years of age) it is used 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.

Daptomycin Lupin will not work against infections that cause pneumonia (a serious infection or inflammation in the lung tissue).

## 2. What should I know before I use Daptomycin Lupin?

### Warnings

Daptomycin Lupin 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.

**Do not use Daptomycin Lupin if:**

- you are allergic (hypersensitive) to daptomycin, or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can use this medicine.

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 any other medical conditions.
- take any medicines for any other condition.
- 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 Daptomycin Lupin.
- are suffering from diarrhoea.

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, Daptomycin Lupin is not recommended in pregnancy. Your doctor will discuss with you the risks and benefits of having Daptomycin Lupin 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 Daptomycin Lupin.

## 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.

Tell your doctor if you are taking:

- warfarin (a medicine used to prevent blood clots);
- statins or fibrates (medicines used to lower cholesterol);
- ciclosporine (a medicine used to help prevent organ transplant rejection or treat certain problems with the immune system);
- non-steroidal anti-inflammatory drugs (NSAIDs) or COX-2 inhibitors, eg. celecoxib (medicines used to

relieve pain, swelling or other symptoms of inflammation);

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

**Some medicines may interfere with Daptomycin Lupin and affect how it works.**

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

## 4. How do I use Daptomycin Lupin?

Daptomycin Lupin 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 Daptomycin Lupin.

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

### How it is given

- Adults: Daptomycin Lupin 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): Daptomycin Lupin is given directly into the blood stream by infusion (drip) over 30 minutes.
- Children (1-6 years of age): Daptomycin Lupin is given directly into your blood stream by infusion (drip) over 60 minutes.

### If you are given too much Daptomycin Lupin

Since Daptomycin Lupin 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.

## 5. What should I know while using Daptomycin Lupin?

### Things you should do

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

### Call your doctor straight away if you:

- develop itching with swelling or skin rash or difficulty breathing while you are being given Daptomycin Lupin.

Tell your doctor 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 Daptomycin Lupin treatment. The symptoms generally go away within a few days of stopping Daptomycin Lupin.
- **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 Daptomycin Lupin 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 Daptomycin Lupin.

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

**If you get a sore white mouth or tongue while you are being given Daptomycin Lupin 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 Daptomycin Lupin allows fungi to grow and the above symptoms to occur. Daptomycin Lupin does not work against fungi.

**You should tell your doctor that you are being treated with Daptomycin Lupin 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 soon after being given Daptomycin Lupin, tell your doctor.**

**If you are going to have surgery, tell the surgeon or anaesthetist that you are being given Daptomycin Lupin.**

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 being given Daptomycin Lupin.**

**Tell any other doctors, dentists, and pharmacists who treat you that you are being given Daptomycin Lupin.**

## Things you should not do

- **Do not stop receiving Daptomycin Lupin 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 before you drive or use any machines or tools until you know how Daptomycin Lupin affects you.**

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

## Looking after your medicine

Daptomycin Lupin will be stored in the pharmacy or on the hospital ward. The unopened vials of the dry powder will be stored under refrigeration.

## 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 nurse 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"> <li>• Oral thrush (symptoms include a white, furry, sore tongue and mouth).</li> <li>• Vaginal thrush (symptoms include sore and itchy vagina and/or discharge).</li> <li>• Inflammation and irritation of the vagina (vaginitis).</li> <li>• Fungal infections.</li> <li>• Pain, itchiness or redness at the site of administration.</li> <li>• General pain, weakness or tiredness (fatigue).</li> <li>• Trembling.</li> <li>• Decreased appetite.</li> <li>• Dizziness.</li> <li>• Spinning sensation (vertigo).</li> <li>• Headache.</li> <li>• Flushes.</li> <li>• Mild stomach upsets such as indigestion (dyspepsia), feeling sick</li> </ul>	<p><b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b></p>

<p>(nausea), being sick (vomiting) or stomach pain.</p> <ul style="list-style-type: none"> <li>• Abdominal pain, swelling or bloating.</li> <li>• Flatulence.</li> <li>• Constipation or mild diarrhoea.</li> <li>• Taste disturbance.</li> <li>• Eye irritation.</li> <li>• Difficulty in sleeping (insomnia).</li> <li>• Pain in the arms or legs, or joint pain.</li> <li>• Anxiety.</li> <li>• Urinary tract infection.</li> <li>• High or low blood pressure.</li> </ul>	
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### Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"> <li>• Anaphylaxis, a sudden life-threatening allergic reaction with the following 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.</li> <li>• 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).</li> <li>• Unexplained muscle pain, tenderness, weakness or cramps.</li> <li>• Tingling, burning or numbness of arms and hands or legs and feet (paraesthesia).</li> <li>• Loss or difficulty moving the arms and/or legs.</li> <li>• Changes in heart rhythm.</li> <li>• Yellowing of the skin and eyes (jaundice).</li> <li>• Kidney problems, including kidney failure.</li> <li>• Diarrhoea, especially bloody diarrhoea.</li> <li>• Fainting.</li> <li>• Unusual bleeding in the skin and bruising.</li> <li>• Hypersensitivity reactions (serious allergic reactions) such as: <ul style="list-style-type: none"> <li>○ pus-filled bumps that can spread over the body, sometimes with a fever</li> <li>○ shivering or chills</li> <li>○ flushed appearance</li> <li>○ blistering rash (vesiculobullous rash, Stevens Johnson</li> </ul> </li> </ul>	<p><b>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.</b></p>

Syndrome/Toxic Epidermal Necrolysis) ○ swelling of the face, neck and throat ○ fainting ○ cough.	
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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 Daptomycin Lupin.

**Tell your doctor 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](http://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.**

### After you are given Daptomycin Lupin

**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 Daptomycin Lupin may also cause diarrhoea.

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

## 7. Product details

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

### What Daptomycin Lupin contains

<b>Active ingredient (main ingredient)</b>	Daptomycin
<b>Other ingredients (inactive ingredients)</b>	Sodium hydroxide
<b>Potential allergens</b>	Not applicable

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

### What Daptomycin Lupin looks like

Daptomycin Lupin 350 mg is a pale yellow to light brown powder in a clear glass vial (AUST R 383871).

Daptomycin Lupin 500 mg is a pale yellow to light brown powder in a clear glass vial (AUST R 383872).

### Who distributes Daptomycin Lupin

Generic Health Pty Ltd

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