

DAPTOMYCIN ACCORD

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 Daptomycin Accord?

Daptomycin Accord 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 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.

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

2. What should I know before I am given Daptomycin Accord?

Do not use if you have ever had an allergic reaction to any medicine containing daptomycin 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 Daptomycin Accord?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Daptomycin Accord 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 will I be given Daptomycin Accord?

Daptomycin Accord will be given to you by a doctor or nurse as it needs to be given as in injection or infusion into a vein.

More instructions can be found in Section [4. How will I be given Daptomycin Accord?](#) in the full CMI.

5. What should I know while being given Daptomycin Accord?

Things you should do	<ul style="list-style-type: none">• 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 Daptomycin Accord tell your doctor immediately.• Tell our doctor that you are being treated with Daptomycin Accord if you are about to have a blood clotting test or any other blood tests.• If you become pregnant soon after being given Daptomycin Accord, tell your doctor.• Tell the surgeon or anaesthetist that you are being given Daptomycin Accord if you are going to have surgery.
Things you should not do	Do not stop receiving Daptomycin Accord because you are feeling better, unless advised by your doctor.
Driving or using machines	Be careful driving or operating machinery until you know how Daptomycin Accord affects you.

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

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.

Some of the serious side effects are:

- anaphylaxis, a sudden life-threatening allergic reaction with the symptoms: 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)
- 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
- changes in heart rhythm
- yellowing of the skin and eyes (jaundice)
- kidney problems, including kidney failure
- diarrhoea, especially bloody diarrhoea
- fainting
- unusual bleeding in the skin and bruising
- hypersensitivity reactions (serious allergic reactions) such as: pus filled bumps that can spread over the body, sometimes with a fever, shivering or chills, flushed appearance, blistering rash (vesiculobullous rash, with or without mucous membrane involvement (Stevens-Johnson-syndrome (SJS) or Toxic Epidermal necrolysis (TEN))), swelling of the face, neck and throat, fainting, cough, anaphylaxis, angioedema, drug rash with eosinophilia and systemic symptoms (DRESS) and pulmonary eosinophilia) and a serious lung disorder called eosinophilic pneumonia.

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 ACCORD

Active ingredient(s): *daptomycin*

Consumer Medicine Information (CMI)

This leaflet provides important information about using Daptomycin Accord. **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 [medicine name].**

Where to find information in this leaflet:

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

1. Why am I being given Daptomycin Accord?

Daptomycin Accord contains the active ingredient *daptomycin*. Daptomycin Accord 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.

Daptomycin Accord 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.

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

2. What should I know before I am given Daptomycin Accord?

Warnings

You must not be given Daptomycin Accord if:

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

Daptomycin Accord 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.

Tell your doctor if you:

- are allergic to any other medicines, foods, dyes or preservatives
- have or have had kidney problems. Your doctor may

need to change the dose of Daptomycin Accord

- 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

Tell your doctor if you:

- are pregnant, or intend to become pregnant
- are breastfeeding or plan to breastfeed.

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

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

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 and Daptomycin Accord may interfere with each other.

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.

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 Accord.

4. How will I be given Daptomycin Accord?

Daptomycin Accord 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.

Adults: Daptomycin Accord 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 Accord is given directly into the blood stream by infusion (drip) over 30 minutes.

Children (1-6 years of age): Daptomycin Accord is given

directly into your blood stream by infusion (drip) over 60 minutes.

How much will be given

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

- 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.

When will Daptomycin Accord be given

If you have kidney problems, you may receive Daptomycin Accord less often, e.g. every other day.

- If you are receiving dialysis, and your next dose of Daptomycin Accord is due on a dialysis day, you will usually be given Daptomycin Accord after the dialysis session.

If you receive too much Daptomycin Accord

Since Daptomycin Accord 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. If you think that you have been given too much Daptomycin Accord.

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, nurse, or pharmacist.

5. What should I know while being given Daptomycin Accord?

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 Daptomycin Accord tell 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 Daptomycin Accord treatment. The symptoms generally go away within a few days of stopping Daptomycin Accord

- **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 Accord 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 Accord.

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

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

You should tell your doctor that you are being treated with Daptomycin Accord 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 Accord, tell your doctor.

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

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 Accord.

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

Things you should not do

Do not stop receiving Daptomycin Accord 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 Daptomycin Accord affects you.

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

Looking after your medicine

The hospital will store Daptomycin Accord under the correct conditions.

Getting rid of any unwanted medicine

Your doctor or pharmacist will dispose of any Daptomycin Accord that may be left over.

Do not use this medicine after the expiry date.

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.

Common side effects

Less serious side effects	What to do
<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 infectionspain, itchiness or redness at the site of administrationgeneral pain, weakness or tiredness (fatigue)tremblingdecreased appetitedizzinessspinning sensation (vertigo)headacheflushesmild stomach upsets such as indigestion (dyspepsia), feeling sick (nausea), being sick (vomiting) or stomach painabdominal pain, swelling or bloatingflatulenceconstipation or mild diarrhoeataste disturbanceeye irritationdifficulty in sleeping (insomnia)pain in the arms or legs, or joint painanxietyurinary tract infectionhigh or low blood pressure	Speak to your doctor if you have any of these common side effects and they worry you.

Serious side effects

Serious side effects	What to do
<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,	Call your doctor straight away or go straight to the Emergency Department at

Serious side effects	What to do
<ul style="list-style-type: none">shortness of breath, wheezing or trouble breathingdifficulty breathing, new or worsening cough, new or worsening fever (these may be the signs of a rare, but serious lung disorder called eosinophilic pneumonia)unexplained muscle pain, tenderness, weakness or crampstingling, burning or numbness of arms and hands or legs and feet (paraesthesia)loss or difficulty moving the arms and/or legschanges in heart rhythmyellowing of the skin and eyes (jaundice)kidney problems, including kidney failurediarrhoea, especially bloody diarrhoeafaintingunusual bleeding in the skin and bruisinghypersensitivity reactions (serious allergic reactions) such as:<ul style="list-style-type: none">pus filled bumps that can spread over the body, sometimes with a fevershivering or chillsflushed appearanceblistering rash (vesiculobullous rash, with or without mucous membrane involvement (Stevens-Johnson-syndrome (SJS) or Toxic Epidermal necrolysis (TEN)))swelling of the face, neck and throatfaintingcough.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 Accord	your nearest hospital

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 Daptomycin Accord contains

Active ingredient (main ingredient)	daptomycin
Other ingredients (inactive ingredients)	sodium hydroxide

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

What Daptomycin Accord looks like

Daptomycin Accord is a pale yellow to light brown powder supplied in a vial. (350 mg: AUST R 315391, 500 mg: AUST R 315393).

Who distributes Daptomycin Accord

Accord Healthcare Pty Ltd
Level 24, 570 Bourke Street
Melbourne, VIC, 3000
Australia

This leaflet was prepared in March 2022.