

DAPTOMYCIN ACCORD

Daptomycin Powder for Injection 350 mg and 500 mg

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Daptomycin Accord.

It does not contain all the available information. It does not take the place of talking to your doctor, nurse or pharmacist. All medicines have risks and benefits. Your doctor has weighed the risks of you being given this medicine against the benefits they expect it will have for you.

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

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

What Daptomycin Accord is used for

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).

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.

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

Your doctor may have prescribed it for another purpose.

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

Daptomycin Accord is not addictive.

Before you are given it

When you must not be given it

You must not have 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.

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.

Before you are given it

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 any kidney problems. Your doctor may need to change the dose of Daptomycin Accord

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

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

Taking other medicines or treatments

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

These medicines may be affected by Daptomycin Accord, 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 them before you are given this medicine.

How it is given

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. 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 Accord. 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.

How it is given

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.

If you receive too much (Overdose)

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. Your doctor, nurse or pharmacist will be monitoring your progress and checking the medicine that you are given.

Please contact the Poisons Information Centre (telephone 13 11 26, for advice on overdose Management.

While you are being given it

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 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 must 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.

Things to be careful of

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.

Side Effects

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

Daptomycin Accord helps most people with certain 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.

Tell your doctor or nurse if you notice any of the following and they worry you:

- 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
- pain, itchiness or redness at the site of administration
- general pain, weakness or tiredness (fatigue)
- trembling
- decreased appetite
- dizziness
- spinning sensation (vertigo)
- headache
- flushes
- mild stomach upsets such as indigestion (dyspepsia), feeling sick (nausea), being sick (vomiting) or stomach pain
- abdominal pain, swelling or bloating
- flatulence
- constipation or mild diarrhoea
- taste disturbance
- eye irritation
- difficulty in sleeping (insomnia)
- pain in the arms or legs, or joint pain
- anxiety
- urinary tract infection
- high or low blood pressure

Tell your doctor or nurse immediately if you notice any of the following:

- 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)
- 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)
 - swelling of the face, neck and throat
 - fainting
 - cough.

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.

Tell your doctor if you notice anything else that is making you feel unwell.

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

After being given it

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 Accord 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 Daptomycin Accord 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 the medicine where children cannot reach it.

Product Description

What it looks like

Daptomycin Accord comes in a 20 mL glass vial containing a pale yellow to light brown powder.

Ingredients

Active Ingredient:
daptomycin

Inactive Ingredient:
sodium hydroxide

Daptomycin Accord does not contain preservatives or bacteriostatic agents.

Name and Address of the Sponsor

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

Australian Register numbers

350 mg: AUST R 315391

500 mg: AUST R 315393

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This leaflet was prepared on 24 March 2020.