

PFIZER DAPTOMYCIN

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 PFIZER DAPTOMYCIN?

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

2. What should I know before I use PFIZER DAPTOMYCIN?

Do not use if you/your child have had an allergic reaction to daptomycin or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you/your child have any other medical conditions, take any other medicines, or if you are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I use PFIZER DAPTOMYCIN?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with PFIZER DAPTOMYCIN 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 PFIZER DAPTOMYCIN given?

PFIZER DAPTOMYCIN will be given to you by a doctor or a nurse as an injection or infusion into a vein. The dose will depend on age, bodyweight and the type of infection being treated.

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

5. What should I know during treatment with PFIZER DAPTOMYCIN?

Things you should do	<ul style="list-style-type: none">● Remind any doctor or dentist you visit that you are using PFIZER DAPTOMYCIN.● Tell your doctor if you develop a sore white mouth or tongue; if you become pregnant; if you develop a skin
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	<p>rash, difficulty breathing, diarrhoea, aching muscles, muscle weakness, tingling of the hands/feet, loss of feeling or difficulties in moving, new or worsening fever or cough.</p>
<p>Things you should not do</p>	<ul style="list-style-type: none"> • Do not stop receiving PFIZER DAPTOMYCIN because you are feeling better unless advised by your doctor.
<p>Driving or using machines</p>	<ul style="list-style-type: none"> • Be careful driving or operating machinery until you know how PFIZER DAPTOMYCIN affects you. • PFIZER DAPTOMYCIN may cause dizziness or tiredness in some people.
<p>Looking after your medicine</p>	<ul style="list-style-type: none"> • Store in original carton at below 25°C until ready for use.

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

6. Are there any side effects?

Side effects of this medicine may include oral or vaginal thrush; inflammation and irritation of the vagina; fungal infections; pain; itchiness or redness at the injection site; tiredness; trembling; decreased appetite; dizziness, blurred vision, lightheadedness; spinning sensation; headache; flushes; mild stomach upsets such as indigestion, nausea, vomiting; abdominal swelling or bloating; flatulence; constipation, diarrhoea; taste disturbance; eye irritation; difficulty in sleeping; anxiety; urinary tract infection; 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 or fever; unexplained muscle tenderness, weakness or cramps; tingling, burning or numbness of arms, hands, legs or feet; difficulty moving the arms and/or legs; changes in heart rhythm; yellowing of the skin and eyes; kidney problems or failure; fainting; unusual bleeding in the skin and bruising; pus filled bumps; shivering or chills; blistering rash.

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.

PFIZER DAPTOMYCIN Powder for Injection

Active ingredient(s): *daptomycin*

Consumer Medicine Information (CMI)

This leaflet provides important information about PFIZER DAPTOMYCIN. **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 PFIZER DAPTOMYCIN.**

Where to find information in this leaflet:

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

1. Why am I using PFIZER DAPTOMYCIN?

PFIZER DAPTOMYCIN contains the active ingredient *daptomycin*. PFIZER DAPTOMYCIN is an antibiotic.

PFIZER DAPTOMYCIN is used to treat complicated infections of the skin, infections of the tissues under the skin, blood infections and infections of tissues that line the inside of the heart (including heart valves).

2. What should I know before treatment with PFIZER DAPTOMYCIN?

Warnings

Do not use PFIZER DAPTOMYCIN if:

1. you/your child are allergic to daptomycin, or any of the ingredients listed at the end of this leaflet.
2. Always check the ingredients to make sure you can use this medicine.

Check with your doctor if you/your child:

- are allergic to any other medicines, foods, dyes or preservatives
- have or have had any kidney problems
- are suffering from diarrhoea
- take any medicines for any other condition.

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, PFIZER DAPTOMYCIN is not recommended in pregnancy. Your doctor will discuss with you the risks and benefits of having PFIZER DAPTOMYCIN during pregnancy.

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

You should not breastfeed your child during your treatment with PFIZER DAPTOMYCIN.

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 PFIZER DAPTOMYCIN and affect how it works.

- Warfarin (a medicine used to prevent blood clots)
- Statins or fibrates (medicines used to lower cholesterol)
- Ciclosporin (a medicine used to help prevent organ transplant rejection or to treat certain problems with the immune system)
- 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 PFIZER DAPTOMYCIN.

4. How is PFIZER DAPTOMYCIN given?

How much will be given

- 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, how much the child weighs, and the type of infection being treated.

How long will PFIZER DAPTOMYCIN need to be given?

- Your doctor will decide how long you/your child will receive PFIZER DAPTOMYCIN.

If too much PFIZER DAPTOMYCIN is given

Since PFIZER DAPTOMCYIN 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. However, if you think that you/your child have been given too much PFIZER DAPTOMCYIN, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor or nurse, 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 during treatment with PFIZER DAPTOMYCIN?

Things you should do

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

Tell your doctor if you get a sore white mouth or tongue while you are being given PFIZER DAPTOMYCIN or soon after stopping it. 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 PFIZER DAPTOMYCIN allows fungi to grow and the above symptoms occur. PFIZER DAPTOMYCIN does not work against fungi.

Tell your doctor that you are being treated with PFIZER DAPTOMYCIN 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 PFIZER DAPTOMYCIN, tell your doctor.

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

It may affect other medicines used during surgery.

Call your doctor straight away if you develop:

- itching with swelling or skin rash or difficulty breathing while you are being given PFIZER DAPTOMYCIN
- tender or aching muscles or muscle weakness
- any unusual tingling or numbness of the hands or feet, loss of feeling or difficulties in moving
- diarrhoea, especially if you notice blood
- new or worsening fever, cough or difficulty breathing

Remind any doctor or dentist you visit that you are using PFIZER DAPTOMYCIN.

Things you should not do

- **Do not stop receiving PFIZER DAPTOMYCIN 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 PFIZER DAPTOMYCIN affects you.

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

Drinking alcohol

No information available.

Looking after your medicine

PFIZER DAPTOMYCIN is stored in the pharmacy or in a hospital which is responsible for storing and disposing of any unused product correctly.

PFIZER DAPTOMYCIN should be stored in the original carton below 25°C.

When to discard your medicine

Discard any medicine that has passed the expiry date.

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.

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.

Side effects	What to do
<ul style="list-style-type: none">● a white, furry, sore tongue and mouth (oral thrush)● sore and itchy vagina and/or discharge (vaginal thrush)● 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	<p>Speak to your doctor if you have any of these side effects and they worry you.</p>

Side effects	What to do
<ul style="list-style-type: none"> ● decreased appetite ● dizziness, lightheadedness, blurred vision ● 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 ● burning sensation when passing urine, increased 	

Side effects	What to do
<p>urge to urinate, cloudy or dark urine, lower abdominal pain (urinary tract infection)</p>	
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, 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 	<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>

Side effects	What to do
<p>hands or legs and feet (paraesthesia)</p> <ul style="list-style-type: none"> ● loss or difficulty moving the arms and/or legs ● changes in heart rhythm, fast heart beat, chest pain ● yellowing of the skin and eyes ● (jaundice) ● swelling in the legs, ankles, or feet, little or no urine, drowsiness, nausea, vomiting, breathlessness (kidney problems, including kidney failure) ● diarrhoea, especially bloody diarrhoea ● fainting ● unusual bleeding in the skin and bruising <p>Hypersensitivity reactions (serious allergic reactions) with symptoms such as:</p> <ul style="list-style-type: none"> ● pus filled bumps that can spread over the 	

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. 	

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 PFIZER DAPTOMYCIN contains

Active ingredient (main ingredient)	Daptomycin
Other ingredients (inactive ingredients)	Citric acid; sodium hydroxide; water for injections

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

What PFIZER DAPTOMYCIN looks like

PFIZER DAPTOMYCIN is a light yellow to light brown powder in a clear glass vial that will be dissolved to a clear yellow to light brown solution before it is given to you.

Australian Registration Numbers:

AUST R 373705 (350 mg vial)

AUST R 373704 (500 mg vial)

Who distributes PFIZER DAPTOMYCIN

Pfizer Australia Pty Ltd

Sydney NSW

Toll Free Number: 1800 675 229

www.pfizer.com.au

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