

## READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

### PATIENT MEDICATION INFORMATION

#### Daptomycin for Injection

Read this carefully before you start taking **Daptomycin for Injection** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **Daptomycin for Injection**.

#### What is **Daptomycin for Injection** used for?

**Daptomycin for Injection** is used to treat bacterial infections:

- of the skin and soft tissues (patients 1 year and older)
- in the blood (patients 1 year and older)
- certain heart valve infections (patients 18 years and older)

Antibacterial drugs like **Daptomycin for Injection** treat only infections caused by bacteria. They do not treat viral infections. Although you may feel better early in treatment, **Daptomycin for Injection** should be used exactly as directed. Misuse or overuse of **Daptomycin for Injection** could lead to growth of bacteria that will not be killed by **Daptomycin for Injection** (resistance). This means that **Daptomycin for Injection** may not work for you in the future.

#### How does **Daptomycin for Injection** work?

**Daptomycin for Injection** are antibiotics. They work by killing certain bacteria that cause your infection.

#### What are the ingredients in **Daptomycin for Injection**?

Medicinal ingredients: Daptomycin

Non-medicinal ingredients: Sodium hydroxide

#### **Daptomycin for Injection** comes in the following dosage forms:

Lyophilized powder for solution available as 350 mg/vial and 500 mg/vial

#### Do not use **Daptomycin for Injection** if:

- you are allergic to daptomycin.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take **Daptomycin for Injection**. Talk about any health conditions or problems you may have, including if you:

- have kidney or severe liver problems.
- have high blood levels of creatine phosphokinase (CPK).
- are pregnant, or planning on becoming pregnant.
- are breast-feeding or plan to breast-feed. Breast-feeding should be stopped during treatment

with **Daptomycin for Injection**.

- are allergic to any antibiotics or other drugs.
- are taking other medications (see **The following may interact with Daptomycin for Injection**).
- have any questions about your treatment, both before and during treatment.

**Other warnings you should know about:**

Stop taking **Daptomycin for Injection** and contact your doctor right away if you:

- have severe or lasting diarrhea (bloody or watery) with or without
  - fever.
  - stomach pain or tenderness.

You may have Clostridium difficile colitis (bowel inflammation).

**Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.**

**The following may interact with Daptomycin for Injection:**

- Drugs that lower cholesterol (HMG-CoA reductase inhibitors also known as “statins” such as atorvastatin, fluvastatin, lovastatin, pravastatin, rosuvastatin, and simvastatin)
- Tobramycin (another antibiotic)
- Blood thinners (warfarin)

**How to take Daptomycin for Injection:**

**Daptomycin for Injection** will be given intravenously (injected into a vein) by a doctor or nurse in a hospital or clinical setting.

**Usual dose:**

**Adults:**

Serious skin infections: The usual adult dose is 4 mg for every kg of body weight, given as a solution that is injected into a vein. It is given every 24 hours for 7 to 14 days, over either a 30 minute period or a 2 minute period.

Bacterial infections in the blood, including certain heart valve infections: The usual adult dose is 6 mg for every kg of body weight, given as a solution that is injected into a vein. It is given every 24 hours for 10 to 42 days, either over a 30 minute period or a 2 minute period.

**Children:**

Your doctor will decide how much **Daptomycin for Injection** to give your child based on their age, weight and type of infection.

Serious skin infections:

Age Group	Dosage	Duration of
12 to 17 years	5 mg/kg once every 24 hours infused over 30 minutes	Up to 14 days
7 to 11 years	7 mg/kg once every 24 hours infused over 30 minutes	
2 to 6 years	9 mg/kg once every 24 hours infused over 60 minutes	
1 to less than 2 years	10 mg/kg once every 24 hours infused over 60 minutes	

Bacterial infections in the blood:

Age Group	Dosage	Duration of
12 to 17 years	7 mg/kg once every 24 hours infused over 30 minutes	Up to 42 days
7 to 11 years	9 mg/kg once every 24 hours infused over 30 minutes	
1 to 6 years	12 mg/kg once every 24 hours infused over 60 minutes	

**Overdose:**

If you think you have taken too much **Daptomycin for Injection**, contact your healthcare professional, hospital emergency department or regional poison control centre immediately, even if there are no symptoms.

**What are possible side effects from using Daptomycin for Injection?**

These are not all the possible side effects you may feel when taking **Daptomycin for Injection**. If you experience any side effects not listed here, contact your healthcare professional.

Common side effects may include:

- headache or dizziness.
- diarrhea or constipation.
- nausea or vomiting.
- rash or itching.
- difficulty sleeping.

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	

<p><b>UNCOMMON</b></p> <p>A serious allergic reaction with symptoms such as:</p> <ul style="list-style-type: none"> <li>• shortness of breath, difficulty swallowing.</li> <li>• hives, itching, drug rash, blister-like sores.</li> <li>• swelling of the mouth, throat, lips and limbs (angioedema).</li> </ul>		X	
<p>Pain in the hands and feet with symptoms such as:</p> <ul style="list-style-type: none"> <li>• burning, "pins and needles", numbness.</li> <li>• muscle pain, weakness or tiredness (myopathy).</li> </ul>		X	
Irregular heartbeat		X	
<p>Kidney problems with symptoms such as:</p> <ul style="list-style-type: none"> <li>• reduced kidney function, kidney failure.</li> <li>• increased urination, bloody urine.</li> <li>• lower back pain, pressure in the bladder.</li> <li>• fatigue and nausea.</li> </ul>		X	
<p><b>VERY RARE</b></p> <p>Respiratory problems with symptoms such as:</p> <ul style="list-style-type: none"> <li>• fever, cough, shortness of breath or difficulty breathing (eosinophilic pneumonia).</li> <li>• Inflammation of the lungs (organizing pneumonia)</li> </ul>		X	

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, talk to your healthcare professional.

**Reporting Side Effects**

You can report any suspected side effects associated with the use of health products to Health Canada

by:

- Visiting the Web page on Adverse Reaction Reporting ( <https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

*NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.*

**Storage:**

**Daptomycin for Injection** vials containing lyophilized powder should be stored at 2°C to 8°C.

Reconstituted solutions are to be used immediately or refrigerated (2°C to 8°C) and used within 72 hours, then discarded. Health Care professionals should refer to the Product Monograph for more details.

Keep out of reach and sight of children.

**If you want more information about Daptomycin for Injection:**

- Talk to your healthcare professional
- Find the full product monograph that is prepared for health professionals and includes this Patient Medication Information by visiting the Government of Canada website (<https://health-products.canada.ca/dpd-bdpp/index-eng.jsp>), the manufacturer's website (<http://www.pfizer.ca>) or calling 1-800-463-6001.

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