

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS:

S4

Daptomycin Equity, 500 mg, Powder for Solution for Infusion

Daptomycin

Sugar free

Read all of this leaflet carefully before you are given Daptomycin Equity

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.

What is in this leaflet

1. What Daptomycin Equity is and what it is used for
2. What you need to know before you use Daptomycin Equity
3. How to use Daptomycin Equity
4. Possible side effects
5. How to store Daptomycin Equity
6. Contents of the pack and other information

1. What DAPTOMYCIN EQUITY is and what it is used for

The active substance in Daptomycin Equity powder for solution for infusion is daptomycin. Daptomycin is an antibacterial that can stop the growth of certain bacteria.

Daptomycin Equity is used in adults to treat infections of the skin and the tissues below the skin.

Daptomycin Equity is also used in adults to treat infections in the tissues that line the inside of the heart (including heart valves) which are caused by a type of bacteria called *Staphylococcus aureus*. It is also used to treat infections in the blood caused by the same type of bacteria when associated with heart infection.

Depending on the type of infection(s) that you have, your doctor may also prescribe other antibacterials while you are receiving treatment with Daptomycin Equity.

2. What you need to know before you use Daptomycin Equity

Daptomycin Equity should not be administered to you:

- If you are hypersensitive (allergic) to daptomycin or to any other ingredients of Daptomycin Equity (listed in section 6).

Warnings and precautions

Tell your doctor or healthcare provider before being given the injection:

- If you may develop tender or aching muscles or muscle weakness (see section 4 of this leaflet for more information). Your doctor will make sure you have a blood test and will advise whether or not to continue with Daptomycin Equity. The symptoms generally go away within a few days of stopping Daptomycin Equity.
- If you have, or have previously had kidney problems. Your doctor may need to change the dose of Daptomycin Equity (see section 3 of this leaflet).
- If you are very overweight. There is a possibility that your blood levels of Daptomycin Equity could be higher than those found in persons of average weight and you may need careful monitoring in case of side effects.

Tell your doctor straight away if you develop any of the following symptoms:

- Symptoms suggestive of allergic reaction, such as wheezing, difficulty breathing, swelling of the face, neck and throat, rashes and hives, fever (see section 4 of this leaflet for more information). Serious, acute allergic reactions have been observed in patients treated with nearly all antibacterial medicines, including Daptomycin Equity.
 - Diarrhoea, especially if you notice blood or mucus, or if diarrhoea becomes severe or persistent.
 - Any unusual tingling or numbness of the hands or feet, loss of feeling or difficulties with movements.
- Your doctor will decide whether you should continue the treatment.

- New or worsening fever, cough or difficulty breathing. These may be signs of a rare but serious lung disorder called eosinophilic pneumonia. Your doctor will check the condition of your lungs and decide whether or not you should continue Daptomycin Equity treatment.

Daptomycin Equity may interfere with laboratory tests that measure how well your blood is clotting. The results can suggest poor blood clotting when, in fact, there is no problem. Therefore, it is important that your doctor takes into account that you are receiving Daptomycin Equity. Please inform your doctor that you are on treatment with Daptomycin Equity.

Your doctor will perform blood tests to monitor the health of your muscles both before you start treatment and frequently during treatment with Daptomycin Equity.

Children

Daptomycin Equity should not be administered to children below 18 years of age.

Other medicines and Daptomycin Equity

Always tell your healthcare provider if you are taking any other medicine.

(This includes all complementary or traditional medicines.)

It is particularly important that you tell your doctor if you are taking any of the following medicine:

- Oral anti-coagulants (e.g. warfarin), which are medicines that prevent blood from clotting. It may be necessary for your doctor to monitor your blood clotting times.
- Medicines called statins or fibrates (to lower cholesterol) or ciclosporin (a medicine used in transplantation to prevent organ rejection or for other conditions, e.g. rheumatoid arthritis or atopic dermatitis). It is possible that the risk of side effects affecting the muscles may be higher when any of these medicines (and some others that can affect muscles) is taken during treatment with Daptomycin Equity. Your doctor may decide not to give you Daptomycin Equity or to stop the other medicine for a while.
- Pain killing medicines called non-steroidal anti-inflammatory drugs (NSAIDs) or COX-2 inhibitors (e.g.

celecoxib). These could interfere with the effects of Daptomycin Equity in the kidney.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before receiving Daptomycin Equity.

Do not receive Daptomycin Equity during pregnancy or if you are breastfeeding your baby.

Driving and using machines

Daptomycin Equity is not expected to have any effect on your ability to drive or use machines.

It is not always possible to predict to what extent Daptomycin Equity may interfere with your daily activities. As Daptomycin Equity may cause dizziness, you should ensure that you do not engage in driving a vehicle or using machines until you are aware of the measure to which Daptomycin Equity affects you.

3. How to use Daptomycin Equity

You will not be expected to give yourself Daptomycin Equity. It will be given to you by a person who is qualified to do so.

Adults (18 years of age and above):

The dose will depend on how much you weigh and the type of infection being treated. The usual dose for adults is 4 mg for every kilogram (kg) of body weight once daily for skin infections or 6 mg for every kg of body weight once daily for a heart infection or a blood infection associated with heart infection. In adult patients, this dose is given directly into your blood stream (into a vein), either as an infusion lasting about 30 minutes or as an injection lasting about 2 minutes. The same dose is recommended in people aged over 65 years provided their kidneys are working well. If your kidneys do not work well, you may receive Daptomycin Equity less often, e.g. once every other day. If you are receiving dialysis, and your next dose of Daptomycin Equity is due on a dialysis day, you will be usually given Daptomycin Equity after the dialysis session.

Daptomycin Equity should not be given to children under 18 years of age.

If you receive more Daptomycin Equity than you should

Since a healthcare provider will administer Daptomycin Equity, he/she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage.

If a dose of Daptomycin Equity is missed

Since a healthcare provider will administer Daptomycin Equity, it is unlikely that the dose will be missed.

4. Possible side effects

Daptomycin Equity can have side effects.

Not all side effects reported for Daptomycin Equity are included in this leaflet. Should your general health worsen or if you experience any untoward effects while receiving Daptomycin Equity, please consult your healthcare provider for advice.

If any of the following happens, stop receiving Daptomycin Equity and tell your doctor immediately and go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing,
- rash or itching,
- fainting.

These are all very serious side effects. If you have them, you may have had a serious reaction to Daptomycin Equity. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- A serious allergic reaction including anaphylaxis, angioedema, drug rash with eosinophilia and systemic symptoms (DRESS)) has been reported, in some cases during administration of Daptomycin Equity. This serious allergic reaction needs immediate medical attention. Tell your doctor or nurse straight away if

you experience any of the following symptoms:

- chest pain or tightness,
 - rash with blistering, sometimes affecting the mouth and genitals,
 - swelling around throat,
 - rapid or weak pulse,
 - wheezing,
 - fever,
 - shivering or trembling,
 - hot flushes,
 - dizziness,
 - fainting,
 - metallic taste.
- A rare but potentially serious lung disorder called eosinophilic pneumonia has been reported in patients given daptomycin, as contained in Daptomycin Equity, mostly after more than 2 weeks of treatment. The symptoms can include difficulty breathing, new or worsening cough, or new or worsening fever.
 - yellowing of the skin and eyes (jaundice).
 - if you experience unexplained muscle pain, tenderness, or weakness. In very rare cases, muscle problems can be serious, including muscle breakdown (rhabdomyolysis), which can result in kidney damage.

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent side effects:

- fungal infections such as thrush
- urinary tract infection
- candida (type of yeast) infection
- decreased number of red blood cells (anaemia)
- headache
- high or low blood pressure
- constipation, abdominal pain

- diarrhoea, feeling sick (nausea) or being sick (vomiting)
- flatulence
- abdominal swelling or bloating
- higher levels of liver function tests (ALT, AST or ALP)
- pain in arms or legs
- blood testing showing higher levels of creatine phosphokinase (CPK)
- pain, itchiness or redness at the site of infusion, fever, lack of energy

Less frequent side effects:

- presence of fungi or yeast in the blood
- oral or vaginal thrush
- fungal urinary tract infection
- bone infection
- blood disorders (e.g. increased number of small blood particles called platelets, which may increase the tendency for blood clotting or of bleeding, or higher levels of certain types of white blood cells)
- prolonged prothrombin time
- disease of the lymph nodes (swollen and enlarged)
- high levels of disease-fighting white blood cells
- decreased appetite, increased levels of blood sugar, imbalance of electrolytes, low levels of potassium and magnesium in the blood
- anxiety, difficulty in sleeping, seeing and hearing things that don't exist, change of mental status
- tingling or numbness of the hands or feet, taste disturbance
- trembling, involuntary muscle movements
- spinning, ringing in the ears
- eye irritation, blurred vision
- abnormally rapid heart rhythm, irregular heartbeat, a sudden, sometimes temporary, cessation of the heart's functioning (cardiac arrest)
- flushes
- shortness of breath

- indigestion (dyspepsia), inflammation of the tongue
- dry mouth, painful gums, loose stools, numbness in the mouth, inflammation of the mucous membranes of the mouth
- hives, patches of skin become rough and inflamed with blisters which cause itching and bleeding, skin blisters
- muscle pain, cramping, or weakness, inflammation of the muscles (myositis), joint pain, back pain
- blood test showing increased levels of serum creatinine, myoglobin, or lactate dehydrogenase (LDH), blood bicarbonate, blood phosphorus
- kidney problems
- inflammation and irritation of the vagina
- chest pain, general pain or weakness, tiredness (fatigue), swelling in legs or arms
- a sudden feeling of cold with shivering accompanied by a rise in temperature

Side effects with unknown frequency:

- antibacterial-associated diarrhoea
- deficiency of platelets in the blood. This causes bleeding into the tissues, bruising, and slow blood clotting after injury
- weakness, numbness and pain from nerve damage, usually in the hands and feet
- sudden skin eruptions that appear on average five days after a medication is started.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the “**6.04 Adverse Drug Reaction Reporting Form**”, found online under SAHPRA’s publications: <https://www.sahpra.org.za/Publications/Index/8>. By reporting side effects, you can help provide more information on the safety of Daptomycin Equity.

5. How to store Daptomycin Equity

Store all medicines out of reach of children.

Store in a refrigerator (2 °C – 8 °C).

Do not freeze.

After reconstitution: Chemical and physical in-use stability of the reconstituted solution in the vial has been demonstrated for 12 hours at room temperature or up to 48 hours if stored at 2 °C – 8 °C. Chemical and physical stability of the diluted solution in infusion bags is established as 12 hours at room temperature or 48 hours if stored under refrigeration.

Since no preservative or bacteriostatic agent is present in this product, aseptic technique must be used in preparation of final IV solution. Stability studies have shown that the reconstituted solution is stable in the vial for 12 hours at room temperature, or up to 48 hours if stored under refrigeration at 2 °C – 8 °C. The diluted solution is stable in the infusion bag for 12 hours at room temperature, or 48 hours if stored under refrigeration.

Do not use this medicine after the expiry date which is stated on the carton and label after EXP. The expiry date refers to the last day of that month.

Do not use this medicine if you notice visible signs of deterioration.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What Daptomycin Equity contains

The active ingredient is daptomycin.

One ml provides 50 mg of daptomycin after reconstitution with 10 ml of sodium chloride 9 mg/ml (0,9 %) solution.

The other ingredient is sodium hydroxide (to adjust pH).

What Daptomycin Equity looks like and contents of the pack

Before reconstitution: pale yellow to light brown lyophilised cake or powder.

After reconstitution: clear, pale yellow to light brown colour solution free from visible particles.

Daptomycin Equity powder for solution for infusion is filled in a 10 ml Type I glass vial sealed with a lyophilisation type I, grey butyl rubber closure and an aluminium cap with a blue plastic flip-off seal, packed into cartons as single units.

Holder of Certificate of Registration

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The following information is intended for healthcare professionals only

Important: Please refer to the Professional Information before prescribing.

Instructions for use and handling

In adults, Daptomycin Equity may be administered intravenously as an infusion over 30 minutes or as an injection over 2 minutes. Preparation of the solution for infusion requires an additional dilution step as detailed below.

Since no preservative or bacteriostatic agent is present in Daptomycin Equity, aseptic technique must be used in preparation of final IV solution.

The contents of a Daptomycin Equity vial should be reconstituted to 50 mg/ml using aseptic technique as follows:

Note: To minimise foaming, AVOID vigorous agitation or shaking of the vial during or after reconstitution.

1. Remove the polypropylene flip-off cap from the Daptomycin Equity vial to expose the central portion of the rubber stopper.
2. Slowly transfer 10 ml of 0,9 % sodium chloride injection through the centre of the rubber stopper into the Daptomycin Equity vial, pointing the transfer needle toward the wall of the vial.
3. Ensure that the entire Daptomycin Equity product is wetted by gently rotating the vial.
4. Allow the product to stand undisturbed for 10 minutes.
5. Gently rotate or swirl the vial contents for a few minutes, as needed, to obtain a completely reconstituted solution.

For IV injection over a period of 2 minutes, reconstituted Daptomycin Equity is administered at a concentration of 50 mg/ml.

The combined storage time (reconstituted solution in vial and diluted solution in infusion bag) at room temperature should not exceed 12 hours; the combined storage time (reconstituted solution in vial and diluted solution in infusion bag) under refrigeration (2 °C – 8 °C) should not exceed 48 hours. Parenteral medicines

should be inspected visually for particulate matter prior to administration.

Compatible intravenous solutions:

Daptomycin Equity is compatible with 0,9 % sodium chloride injection and Lactated Ringer's injection.

Daptomycin Equity is not compatible with dextrose-containing diluents.

Daptomycin Equity must not be mixed with other medicines except those mentioned above.

Daptomycin Equity vials are for single use only. Any unused portion remaining in the vial should be discarded.