

PATIENT INFORMATION LEAFLET**SCHEDULING STATUS****S4****DAPICUB 500 mg powder for solution for infusion****Daptomycin****Sugar free****Read all of this leaflet carefully before you are given DAPICUB**

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

What is in this leaflet

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

1. What DAPICUB is and what it is used for

Daptomycin is an antibacterial that can stop the growth of certain bacteria. DAPICUB is used in adults to treat infections of the skin and the tissues below the skin. It is also used to treat infections in the blood when associated with skin infection.

DAPIBUB 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 that you have, your doctor may also prescribe other antibacterial while you are receiving treatment with DAPICUB.

2. What you need to know before you use DAPICUB

DAPICUB should not be administered to you:

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

Warnings and precautions

Tell your doctor or health care provider before being given the injection:

- If you have, or previously had kidney problems. Your doctor may need to change the dose of DAPICUB (see section 3 of this leaflet).
- If you have a disease where your muscles do not function properly, resulting in muscle weakness (myopathy).
- If you are very overweight. There is a possibility that your blood levels of DAPICUB could be higher than those found in persons of average weight and you may need careful monitoring in case of side effects.
- If you are taking medicines for blood clotting. DAPICUB may interfere with laboratory tests that measure how well your blood is clotting.

If any of these applies to you, tell your doctor or nurse before you are given DAPICUB.

Special care should be taken with DAPICUB:

- If you have a serious, acute allergic reactions. Tell a doctor or a nurse immediately if you experience 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).

- If you develop tender or aching muscles or muscle weakness (see section 4 of this leaflet for more information). If this happens tell your doctor. Your doctor will make sure you have a blood test and will advise whether or not to continue with DAPICUB. The symptoms generally go away within a few days of stopping DAPICUB.
- If you have any unusual tingling or numbness of the hands or feet, loss of feeling or difficulties with movements. If this happens, tell your doctor who will decide whether you should continue the treatment.
- If you have diarrhea, especially if you notice blood or mucus, or if diarrhea becomes severe or persistent.
- If you have 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 with DAPICUB treatment.

Children and adolescents

DAPICUB should not be given to children or adolescents younger than 18 years old.

Other medicines and DAPICUB

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

Tell your doctor or health care provider if you are taking any of the following:

- 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 DAPICUB. Your doctor may decide not to give you DAPICUB 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 DAPICUB in the kidney.
- 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.

Pregnancy and breastfeeding

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 health care provider for advice before taking this medicine.

DAPICUB should not be used when you are pregnant or breastfeeding.

Driving and using machines

It is not always possible to predict to what extent DAPICUB may interfere with your daily activities. First ensure that you are aware of the measure to which DAPICUB affects you before you engage in the above activities.

3. How to use DAPICUB

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

You will be given DAPICUB intravenously as an infusion.

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 skin or heart infection. In adult patients, this dose is given directly into your blood stream (into a vein), as an infusion lasting about 30 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 DAPICUB less often, e.g. once every other day. If you are receiving dialysis, and your next dose of DAPICUB is due on a dialysis day, DAPICUB will usually be given after the dialysis session.

Detailed instructions for use and handling are given in section 6.

If you had been given more DAPICUB than you should receive

Since a health care provider will administer DAPICUB, he/she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage.

4. Possible side effects

DAPICUB can have side effects.

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

If any of the following happens, tell your doctor immediately or go to the casualty department at your nearest hospital:

- Chest pain or tightness,
- Rash with blistering, sometimes affecting the mouth and genitals,

- Swelling around throat,
- Rapid or weak pulse,
- Wheezing

These are all very serious side effects. If you have them, you may have had a serious reaction to DAPICUB, and you may need urgent medical attention.

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

- Rapid heartbeat (tachycardia)
- Wheezing
- Raised body temperature with or without flushing
- A sudden feeling of cold with shivering accompanied by a rise in temperature, often with copious sweating
- A sensation of spinning dizziness
- Loss of consciousness
- Metallic taste
- Rash

These are all serious side effects. You may have a reaction to the infusion and needs medical attention.

Tell your doctor if you notice any of the following:

Frequent

- Fungal infections e.g. thrush, urinary tract infection
- Decreased number of red blood cells (anemia)
- Anxiety, difficulty to sleep
- Dizziness, headache
- High or low blood pressure
- Abdominal pain, nausea, vomiting, constipation, diarrhoea, flatulence,

abnormal swelling, bloating, indigestion

- Abnormal liver function tests
- Limb pain, increased levels of an enzyme found in muscle tissue (creatine phosphokinase) in your blood.
- Itchy rash of skin (eczema), skin become inflamed, itchy, red, cracked, and rough.

Less frequent

- Blood disorders (e.g. increased number of small blood particles called platelets, which may increase the tendency for blood clotting, or higher levels of certain types of white blood cells), lymphadenopathy (a disease affecting the lymph nodes)
- Decreased appetite, excess glucose in the blood stream, imbalanced electrolytes
- An experience involving the apparent perception of something not present (hallucinations), change in your mental status
- Tingling or numbness of the hands or feet
- Eye irritation, blurred vision
- Noise or ringing in the ears (tinnitus)
- Rapid or irregular heartbeat
- Shortness of breath
- Indigestion, inflammation of the tongue, dry mouth
- Jaundice
- Muscle pain, cramping, or weakness, inflammation of the muscles (myositis), joint pain
- Kidney problems
- Vaginitis

- Feeling of tiredness or have a lack of energy, weakness, chest pain, a sudden feeling of cold with shivering accompanied by a rise in temperature, often with sweating, especially at the onset or height of a fever
- Uncontrollable movements of the body, which can cause twitching or restlessness
- Inflammation of the mucous membranes of the mouth, pain of the gums, loss of sensation in the mouth
- Taste disorder
- The presence of abnormal quantities of protein in the urine, which may indicate damage to the kidneys.

Frequency unknown

- Cough
- Eosinophilic pneumonia (a lung disease in which a type of white blood cells) appear in increased numbers in the lungs and usually in the bloodstream)

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 DAPICUB.

5. How to store DAPICUB

Store all medicines out of reach of children.

- Store between 2 °C to 8 °C (in a refrigerator)
- Keep the vial in the outer carton
- Do not use after the expiry date stated on the label/carton

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 DAPICUB contains

- The active substance is daptomycin. One vial of powder contains 500 mg daptomycin.
- The other ingredient is sodium hydroxide (for adjusting the pH).

What DAPICUB looks like and contents of the pack

Before reconstitution: DAPICUB is a pale yellow to light brown cake or powder.

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

DAPICUB is supplied in single-use clear glass vials with rubber stoppers and aluminium flip top seal.

The vials are packed in single units.

Holder of Certificate of Registration

Kahma Biotech (Pty) Ltd

106, 16th Road

Midrand

This leaflet was last revised in

14 March 2023

Registration number

550096

Access to the corresponding Professional Information

To be confirmed.