

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: **S4**

CUBACT™, 500 mg, powder for solution for infusion

Daptomycin

Sugar free

Read all of this leaflet carefully before you are given CUBACT

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

1. What CUBACT is and what it is used for

CUBACT is an antibacterial medicine. The active substance, daptomycin, belongs to a group of medicines called antibiotics. It works by stopping the growth of certain bacteria, thereby causing the death of the bacterial cells.

CUBACT may be used in adults to treat certain complicated bacterial infections of the skin and the tissues below the skin. It may also be used to treat certain infections of the blood.

Depending on the type of infection you have, your doctor may also prescribe other antibacterial medicines.

2. What you need to know before you use CUBACT

CUBACT should not be administered to you, if you:

- are hypersensitive (allergic) to daptomycin or any of the other ingredients of CUBACT;
- have pneumonia (infection of the lungs);
- are below 18 years of age.

Warnings and precautions

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

Special care should be taken with CUBACT:

- if you have, or have previously had, kidney problems (your doctor may need to adapt your dose);
- what other medicines you are taking. Some medicines may also cause muscle pain and weakness (see *Other medicines with CUBACT* and section 4).

Serious side effects may occur in some people when treated with CUBACT. See section 4 for possible side effects that require immediate attention.

If you have any of the following symptoms, tell your doctor immediately:

- Severe allergic reactions causing difficulty in swallowing or breathing and/or severe skin reactions (blistering, peeling, hives) have been reported. Tell your doctor immediately if you have these reactions (see section 4).
- Severe, persistent diarrhoea (loose bowels), with blood or mucous in the stools and abdominal pain and cramps have been reported. These symptoms may be due to a side effect known as pseudomembranous colitis (*C. difficile* colitis). This is a condition where the

colon is inflamed due to an overgrowth of the bacterium *Clostridium difficile*. If not treated immediately, it may be life-threatening.

- Tender or aching muscles or muscle weakness, which may be severe and could be due to rhabdomyolysis. Rhabdomyolysis is a condition that occurs due to the breakdown of muscle tissue, thereby releasing myoglobin into the bloodstream. If you have too much myoglobin in your blood, it can cause kidney damage.
- Unusual tingling or numbness of the hands or feet, loss of feeling or difficulties with movements (peripheral neuropathy).
- New or worsening cough, fever, difficulty breathing and sweating at night (eosinophilic pneumonia). Your doctor will check the condition of your lungs and decide whether you should continue CUBACT treatment.

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

Daptomycin may interfere with laboratory tests that measure how well your blood is clotting. The results can suggest poor blood clotting even if there is no problem. It is therefore important that your doctor considers that you are receiving CUBACT. Please inform the laboratory staff that you are on treatment with CUBACT.

Children and adolescents

Do not give CUBACT to children and adolescents as safety and efficacy have not been established.

Use in elderly

People over the age of 65 can be given the same dose as other adults, provided their kidneys are working well.

Other medicines and CUBACT

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

This is especially important with the following medicines:

- Medicines called statins or fibrates (to lower cholesterol). 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 CUBACT. Your doctor may decide not to give you CUBACT or to stop the other medicine for a while.
- Ciclosporin (a medicine used in transplantation to prevent organ rejection or for other conditions, e.g. rheumatoid arthritis or atopic dermatitis).
- Pain killing medicines called non-steroidal anti-inflammatory drugs (NSAIDs) or COX-2 inhibitors (e.g. celecoxib). These could interfere with the effects of CUBACT 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.
- Laboratory test reagents for PT/INR testing.
- Tobramycin, or any other antibiotic medicine, including rifampicin (used for the treatment of TB (tuberculosis)).

Pregnancy and breastfeeding

If you are pregnant or breastfeeding your baby, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare professional for advice before CUBACT is administered to you.

Safety in pregnancy and breastfeeding has not been established.

CUBACT should therefore not be used during pregnancy or if you breastfeed your baby.

Driving and using machines

CUBACT may make you feel dizzy. Do not drive or use tools or machines as CUBACT could interfere with your ability to drive safely.

3. How to use CUBACT

Do not share medicines prescribed for you with any other person.

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

CUBACT is not intended for children younger than 18 years.

CUBACT is dissolved in a sodium chloride intravenous solution for injection. This solution is then infused (dripped) into a large vein. The infusion will last about 30 minutes. It is usually given once daily for up to 14 days.

Your doctor will decide on the dose to use and the duration of the treatment. This will depend on your condition and the type of infection.

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.

The same dose is recommended in the elderly, provided their kidneys are working well.

If your kidneys do not work well, you may receive CUBACT less often, e.g. once every other day. If you are receiving dialysis, and your next dose of CUBACT is due on a dialysis day, you will usually be given CUBACT after the dialysis session.

If you have the impression that the effect of CUBACT is too strong or too weak, tell your doctor or pharmacist.

If you receive more CUBACT than you should

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

If you forget to use CUBACT

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

If you stop using CUBACT

Since a healthcare provider will administer CUBACT, it is unlikely that treatment will be stopped too soon.

4. Possible side effects

CUBACT can have side effects.

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

If any of the following happens, tell your doctor or healthcare professional immediately:

- Severe allergic reactions: wheezing, difficulty breathing, swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing; or rashes, hives, red skin with fever.
- Yellowing of the eyes and skin, also called jaundice.
- Any unusual tingling or numbness of the hands or feet, loss of feeling or difficulties with movements (peripheral neuropathy). If this happens, your doctor will decide whether you should continue the treatment.

- Antibiotic-associated inflammation of the bowel, including pseudomembranous colitis (severe or persistent watery diarrhoea containing blood or mucous, together with abdominal pain or fever).
- New or worsening fever, cough or difficulty breathing.
- Swelling and problems to urinate, or to produce urine (renal insufficiency or renal failure).
- Skipped heartbeat, heart palpitations or fluttering or jumping of your heart, cardiac arrest.

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

Tell your doctor if you notice any of the following:

Frequent side effects:

- Urinary tract infection (a strong, persistent urge to urinate, with a burning sensation when urinating)
- Yeast and fungal infections such as thrush
- Anaemia (symptoms may be fatigue and a pale skin)
- Anxiety and difficulty in sleeping
- Dizziness and headache
- High blood pressure or low blood pressure (your blood pressure will be controlled while you are in the hospital)
- Nausea (feeling sick), vomiting (being sick), abdominal pains, flatulence, constipation, bloating, diarrhoea (loose bowels)
- Blood tests may show impaired liver function
- Itching skin, skin rashes
- Pain in the arms and legs, increased serum creatine phosphokinase (CPK test, to determine if tissues are damaged).

Less frequent side effects:

- Blood disorders with high levels of eosinophils (certain white blood cells) and overproduction of platelets in the blood
- Prolonged blood clotting time
- Disease of the lymph nodes (enlargement of lymph nodes, the bean-shaped glands found in the neck, armpits, chest, groin, and abdomen)
- Reactions at the injection site (including a quick heartbeat, fever, weakness, shivers, flushing, feeling faint), tiredness, metallic taste in mouth
- Loss of appetite
- High blood sugar
- Electrolyte imbalance
- Taste disorder
- Tremor
- Tingling or pricking ('pins and needles') of the hands or feet
- Vertigo (feels like a spinning or swaying movement)
- An abnormally rapid or irregular heart rate
- Flushes
- Indigestion
- Inflammation of the tongue
- Hallucinations (seeing and hearing things that do not exist)
- Weak muscles, muscle pain, joint pain
- Fatigue
- Pain at injection site
- Protein in the urine (seen with laboratory test)
- Swelling, weakness, chest pain.

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 CUBACT.

5. How to store CUBACT

Store all medicines out of reach of children.

Store in a refrigerator (2 - 8 °C). Do not freeze.

Do not use this medicine after the expiry date which is stated on the carton and label after EXP.

After reconstitution: Chemical and physical in-use stability of the reconstituted solution in the vial has been demonstrated as up to 12 hours at 25 °C and up to 48 hours at 2 - 8 °C.

After dilution: Chemical and physical stability of the diluted solution in infusion bags is established as up to 12 hours at 25 °C or up to 24 hours at 2 - 8 °C.

For the 30-minute intravenous infusion, the combined storage time (reconstituted solution in vial and diluted solution in infusion bag) at 25 °C should not exceed 12 hours (or 24 hours at 2 - 8 °C).

From a microbiological point of view the product should be used immediately. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user and would normally not be longer than 24 hours at 2 - 8 °C.

Do not use CUBACT if you notice any change in the aspect of the product (signs of humidity or presence of particles with a different colour in the powder, or presence of particles, turbidity or precipitate when the solution is reconstituted).

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 CUBACT contains

- The active substance is daptomycin. Each vial contains 500 mg 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.

What CUBACT looks like and contents of the pack

CUBACT powder for solution for infusion is supplied as a pale yellow to light brown, sterile lyophilised powder. It is mixed with a solvent to form a liquid before it is administered.

The reconstituted solution is dark yellow to light brown, free of visible particles.

CUBACT is packed in 15 or 20 ml type I clear glass vials with grey bromobutyl rubber stoppers, closed with an aluminium/polypropylene flip-off seal.

Available in cartons containing 1 or 5 vials.

Not all packing sizes may be marketed.

Holder of Certificate of Registration

Abex Pharmaceutica (Pty) Ltd

Suite C, Rubenstein Ridge

617 Rubenstein Drive

Moreleta Park, 0181

South Africa

Tel: +27 (0) 12 997 6974

This leaflet was last revised in

18 October 2022

Registration number

53 / 20.1.1 / 0433.432

Access to the corresponding Professional Information

Please refer to the SAHPRA repository for Professional Information and Patient Information

Leaflets: <https://www.sahpra.org.za/pi-pil-repository/>.