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LAETUS

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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.

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Please refer to the SAHPRA repository for Professional Information and Patient Information Leaflets:
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PASIËNTINLIGTINGSBLAD

SKEDULERINGSTATUS: S4

CUBACT™, 500 mg, poeier vir oplossing vir infusie
Daptomisien
Suikervry

Lees die hele inligtingsblad sorgvuldig deur voordat CUBACT aan jou gegee word
- Hou hierdie inligtingsblad. Dit mag nodig wees dat jy dit weer wil lees.
- Indien jy verdere vrae het, raadpleeg asseblief jou dokter, apteker, verpleegster of ander gesondheidsorgverskaffer.

Wat is in hierdie pamflet

1. **Wat CUBACT is en waarvoor dit gebruik word**
2. **Wat jy moet weet voordat jy CUBACT gebruik**
3. **Hoe om CUBACT te gebruik**
4. **Moontlike newe-effekte**
5. **Hoe om CUBACT te bewaar**
6. **Inhoud van die pakkie en ander inligting**

1. Wat CUBACT is en waarvoor dit gebruik word

CUBACT is 'n antibakteriële medisyne. Die aktiewe bestanddeel, daptomisien, behoort tot 'n groep medisynes genaamd antibiotika. Dit werk deur die groei van sekere bakterieë te stop, waardeur dit die afsterwe van die bakteriële selle veroorsaak. CUBACT kan by volwassenes gebruik word om sekere gekompliseerde bakteriële infeksies van die vel en die weefsels onder die vel te behandel. Dit kan ook gebruik word om sekere bloedinfeksies te behandel. Afhangende van die tipe infeksie wat jy het, kan jou dokter ook ander antibakteriële medisyne voorskryf.

2. Wat jy moet weet voordat jy CUBACT gebruik

CUBACT moet nie aan jou toegedien word nie indien jy:
- hipersensitief (allergies) is vir daptomisien of vir enige van die ander bestanddele van CUBACT;
- pneumonie (longinfeksie) het;
- onder 18 jarige ouderdom is.

Waarskuwings en voorsorgmaatreëls

Lig jou dokter of gesondheidsorgverskaffer in voordat jy die inspuiting ontvang:
Spesiale voorsorg moet getref word met CUBACT:
- as jy nierprobleme het, of voorheen gehad het (jou dokter sal dalk jou dosis moet aanpas);
- as jy ander medisyne neem. Sekere medisynes kan ook spierpyn en -swakheid veroorsaak (kyk *Ander medisyne met CUBACT* en afdeling 4).

Ernstige newe-effekte kan by sommige mense voorkom wanneer hulle met CUBACT behandel word. Kyk afdeling 4 vir moontlike newe-effekte wat onmiddellike aandag benodig.

Lig dadelik jou dokter in indien jy enige van die volgende simptome ervaar:
- Erge allergiese reaksies wat probleme veroorsaak om te sluk of asem te haal en/of erge velreaksies (blaasvorming, vervelling, netelroos) is aangemeld. Lig jou dokter dadelik in as jy hierdie reaksies het (kyk afdeling 4).
- Erge, volgehoue diarree (los stoelgange), met bloed of slym in die ontlasting en buikpyn en krampe is aangemeld. Hierdie simptome kan wees as gevolg van 'n newe-effek bekend as pseudomembraneuse kolitis (*C. difficile* kolitis). Dit is 'n siektetoestand waar die dikderm ontsteek is as gevolg van 'n oorgroei van die bakterie *Clostridium difficile*. Indien dit nie dadelik behandel word nie, kan dit lewensgevaarlik wees.
- Teer of pynlike spiere of spierswakheid, wat ernstig kan wees en te wyte kan wees aan rabdomiolise. Rabdomiolise is 'n toestand wat voorkom as gevolg van die afbraak van spierweefsel, waardeur mioglobien in die bloedstroom vrygestel word. As jy te veel mioglobien in jou bloed het, kan dit nierskade veroorsaak.
- Ongewone tinteling of gevoelloosheid van die hande of voete, verlies van gevoel of moeite met bewegings (perifere neuropatie).
- Nuwe of verergerende hoes, koors, moeilike asemhaling en sweet in die nag (eosinofiliese pneumonie).
  Jou dokter sal die toestand van jou longe kontroleer en besluit of jy die behandeling met CUBACT kan voortsit.

Jou dokter sal bloedtoetse doen om die gesondheid van jou spiere te monitor, sowel voordat jy met die behandeling begin as gereeld tydens die behandeling met CUBACT.

Daptomisien kan inmeng met laboratoriumtoetse wat bepaal hoe goed jou bloed stol. Die resultate kan swak bloedstolling aantoon, selfs al is daar geen probleem nie. Dit is dus belangrik dat jou dokter in ag neem dat jy CUBACT ontvang. Lig asseblief die laboratoriumpersoneel in dat jy met CUBACT behandel word.

Kinders en adolessente
Moenie CUBACT aan kinders en adolessente gee nie aangesien veiligheid en doeltreffendheid nie vasgestel is nie.

Gebruik by bejaardes
Mense ouer as 65 kan dieselfde dosis as ander volwassenes ontvang, mits hul niere goed werk.

Ander medisyne en CUBACT
Lig altyd jou gesondheidsorgverskaffer in as jy enige ander medisyne neem.
(Dit sluit alle komplementêre of tradisionele medisyne in.)

Dit is veral belangrik vir die volgende medisyne:
- Medisyne genaamd statiene of fibrate (om cholesterol te verlaag). Dit is moontlik dat die risiko van newe-effekte wat die spiere affekteer, hoër kan wees wanneer een van hierdie medisynes (en sommige ander wat spiere kan aantas) tydens behandeling met CUBACT geneem word. Jou dokter kan besluit om nie vir jou CUBACT te gee nie of om die ander medisyne vir 'n rukkie te staak.
- Siklosporien ('n medisyne wat tydens oorplanting gebruik word om orgaanverwerping te voorkom of vir ander siektetoestande, bv. rumatoïede artritis of atopiese dermatitis).
- Pynstillende medisyne genoem niesteroïdale anti-inflammatoriese middels (NSAIM's) of COX-2-remmers (bv. selekoksib). Dit kan die uitwerking van CUBACT in die nier beïnvloed.
- Mondelike antistolmiddels (bv. warfarien), wat medisyne is wat voorkom dat bloed stol. Dit kan nodig wees vir jou dokter om jou bloedstollingstye te monitor.
- Laboratorium toetsreagense vir PT/INR-toetsing.
- Tobramisien, of enige ander antibiotiese medisyne, insluitend rifampisien (gebruik vir die behandeling van TB (tuberkulose)).

Swangerskap en borsvoeding
Indien jy swanger is of jou baba borsvoed, dink jy is dalk swanger, of beplan om 'n baba te hê, raadpleeg asseblief jou dokter, apteker of ander gesondheidsorgverskaffer voordat CUBACT aan jou toegedien word. Veiligheid tydens swangerskap en borsvoeding is nie vasgestel nie. CUBACT moet dus nie tydens swangerskap gebruik word of as jy jou baba borsvoed nie.

Bestuur en gebruik van masjinerie
CUBACT kan jou lomerig/duiselig maak. Moenie bestuur of gereedskap of masjinerie gebruik nie omdat CUBACT jou vermoë om veilig te bestuur kan beïnvloed.

3. Hoe om CUBACT te gebruik

Moenie medisyne wat vir jou voorgeskryf is met enige ander persoon deel nie. Daar sal nie van jou verwag word om CUBACT aan jouself toe te dien nie. Dit sal aan jou gegee word deur 'n persoon wat gekwalifiseer is om dit te doen. CUBACT is nie bedoel vir kinders onder 18 jarige ouderdom nie.
CUBACT word opgelos in 'n natriumchloried intraveneuse oplossing vir inspuiting. Hierdie oplossing word dan in 'n groot aar toegedien (gedrup). Die infusie sal ongeveer 30 minute duur. Dit word gewoonlik een keer daagliks gegee, vir tot en met 14 dae. Jou dokter sal besluit oor die dosis om te gebruik en die duur van die behandeling. Dit sal afhang van jou siektetoestand en die tipe infeksie.
Die dosis sal afhang van hoeveel jy weeg, en die tipe infeksie wat behandel word. Die gewone dosis vir volwassenes is 4 mg vir elke kilogram (kg) liggaamsgewig een keer daagliks vir velinfeksies, of 6 mg vir elke kg liggaamsgewig een keer daagliks vir 'n hartinfeksie of 'n bloedinfeksie wat met vel- of hartinfeksie geassosieer word.
Dieselfde dosis word aanbeveel by bejaardes, mits hul niere goed werk.
As jou niere nie goed werk nie, kan jy CUBACT minder dikwels kry, bv. een keer al om die ander dag. As jy dialise ontvang, en jou volgende dosis van CUBACT is op 'n dialise dag, sal jy gewoonlik CUBACT na die dialisesessie kry. Indien jy die indruk kry dat die effek van CUBACT te sterk of te swak is, lig jou dokter of apteker in.

Indien jy meer CUBACT ontvang as wat jy moes
Aangesien 'n gesondheidsorgverskaffer CUBACT sal toedien, sal hy/sy die dosis beheer. In geval van oordosering sal jou dokter egter die oordosering behandel.

Indien jy vergeet het om CUBACT te gebruik
Aangesien 'n gesondheidsorgverskaffer CUBACT sal toedien, is dit onwaarskynlik dat 'n dosis oorgeslaan sal word.

Indien jy ophou om CUBACT te neem
Aangesien 'n gesondheidsorgverskaffer CUBACT sal toedien, is dit onwaarskynlik dat behandeling te gou gestaak sal word.

4. Moontlike newe-effekte

CUBACT kan newe-effekte hê.
Nie alle newe-effekte wat vir CUBACT aangemeld is, is by hierdie inligtingsblad ingesluit nie. Indien jou algemene gesondheid agteruitgaan of jy enige ongunstige effekte ervaar terwyl jy CUBACT ontvang, raadpleeg asseblief jou dokter, apteker of ander gesondheidsorgverskaffer.

Indien enige van die volgende gebeur, sê dadelik vir jou gesondheidsorgkundige:
- Erge allergiese reaksies: hyging, moeilike asemhaling, swelling van die hande, voete, enkels, gesig, lippe, mond of keel, wat dit moeilik kan maak om te sluk of asem te haal; of uitslag, netelroos, rooi vel met koors.
- Geel verkleuring van die oë, ook bekend as geelsug.
- Enige ongewone tinteling of gevoelloosheid van die hande of voete, verlies van gevoel of moeite met bewegings (perifere neuropatie). As dit gebeur, sal jou dokter besluit of jy met die behandeling moet voortgaan.
- Antibiotikum-geassosieerde ontsteking van die dermkanaal, insluitend pseudomembraneuse kolitis (erge of aanhoudende waterige diarree wat bloed of slym bevat, tesame met buikpyn of koors).
- Nuwe of verslegtende koors, hoes of moeilike asemhaling.
- Swelling en probleme om te urineer, of om urien te produseer (swak nierfunksie of nierversaking).
- Oorgeslaande hartslag, hartkloppings of fladdering of spring van jou hart, hartstilstand.

Hierdie is almal baie ernstige newe-effekte. Indien jy dit ervaar, kan jy moontlik 'n ernstige reaksie op CUBACT hê. Jy kan dringende mediese aandag benodig.

Lig jou dokter in as jy enige van die volgende waarneem:
Gereelde newe-effekte:
- Urienweginfeksie ('n sterk, aanhoudende drang om te urineer, met 'n branderige gevoel wanneer jy urineer)
- Gis- en swaminfeksies soos sproei
- Anemie (simptome kan wees moegheid en 'n bleek vel)
- Angs en sukkel om te slaap
- Duiseligheid en hoofpyn
- Hoë bloeddruk of lae bloeddruk (jou bloeddruk sal gekontroleer word terwyl jy in die hospitaal is)
- Naarheid (siek gevoel), braking (opbring), buikpyne, winderigheid, hardlywigheid, buikopsetting, diarree (los stoelgang)
- Bloedtoetse kan swak lewerfunksie aantoon
- Jeukende vel, veluitslag
- Pyn in die arms en bene, verhoogde serumkreatienfosfokinase (CPK-toets, om te bepaal of weefsels beskadig is).

Minder gereelde newe-effekte:
- Bloedaandoenings met hoë vlakke van eosinofiele (sekere witbloedselle) en oorproduksie van plaatjies in die bloed
- Verlengde bloedstollingstyd
- Aandoening van die limfknope (vergroting van limfknope, die boontjievormige kliere wat in die nek, oksels, bors, lies en buik voorkom)
- Reaksies by die inspuitplek (insluitend 'n vinnige hartklop, koors, swakheid, rillings, gloede, gevoel van floute), moegheid, metaalagtige smaak in die mond
- Verlies van eetlus
- Hoë bloedsuiker
- Elektrolietwanbalans
- Smaakversteuring
- Tremor
- Tinteling of stekelrigheid (speld-en-naaldprikkels) van die hande of voete
- Vertigo (voel soos 'n draaiende of wiegende beweging)
- 'n Abnormaal vinnige of onreëlmatige hartslag
- Gloede
- Swak spysvertering
- Inflammasie van die tong
- Hallusinasies (sien en hoor dinge wat nie bestaan nie)
- Swak spiere, spierpyn, gewrigspyn
- Moegheid
- Pyn by die inspuitplek
- Proteïen in die urien (aangetoon met 'n laboratoriumtoets)
- Swelling, swakheid, borspyn.

Indien jy enige newe-effekte ondervind wat nie in hierdie inligtingsblad genoem word nie, lig asseblief jou dokter of apteker in.

Aanmelding van newe-effekte
Indien jy newe-effekte ondervind, bespreek dit met jou dokter, apteker of verpleegster. Jy kan ook newe-effekte aan SAHPRA rapporteer deur middel van die "**6.04 Adverse Drug Reaction Reporting Form**", wat aanlyn onder SAHPRA se publikasies beskikbaar is: http://www.sahpra.org.za/Publications/Index/8. Deur newe-effekte aan te meld, kan jy help om meer inligting oor die veiligheid van CUBACT te verskaf.

5. Hoe om CUBACT te bewaar

Bewaar alle medisyne buite bereik van kinders.
Bewaar in 'n yskas (2 - 8 °C). Moenie vries nie.
Moenie hierdie medisyne na die vervaldatum gebruik wat op die kartonhouer en die etiket ná EXP. aangedui word nie.
Na hersamestelling:
Chemiese en fisiese stabiliteit tydens gebruik van die aangemaakte oplossing in die flessie is aangetoon as tot 12 uur by 25 °C en tot 48 uur by 2 - 8 °C.
Na verdunning:
Die chemiese en fisiese stabiliteit van die verdunde oplossing in infusiesakke was vasgestel as tot 12 uur by 25 °C of tot 24 uur by 2 - 8 °C.
Vir die 30 minute duur van die intraveneuse infusie, mag die gekombineerde bergingstyd (aangemaakte oplossing in flessie en verdunde oplossing in infusiesak) by 25 °C nie 12 uur (of 24 uur by 2 - 8 °C) oorskry nie.
Vanuit 'n mikrobiologiese oogpunt moet die produk dadelik gebruik word. Indien dit nie dadelik gebruik word nie, is die bergingstye en toestande tydens en voor gebruik die verantwoordelikheid van die gebruiker en sou dit normaalweg nie langer as 24 uur by 2 - 8 °C wees nie.
Moenie CUBACT gebruik as jy enige verandering in die voorkoms van die produk opmerk nie (tekens van vogtigheid of aanwesigheid van deeltjies met 'n ander kleur in die poeier, of aanwesigheid van deeltjies, troebelheid of neerslag wanneer die oplossing aangemaak word).
Neem alle ongebruikte medisyne terug na jou apteker.
Moenie ongebruikte medisyne in afvoerpype of rioolstelsels (bv. toilette) gooi nie.

6. Inhoud van die pakkie en ander inligting

Wat CUBACT bevat
- Die aktiewe bestanddeel is daptomisien. Elke flessie bevat 500 mg daptomisien. Een ml lewer 50 mg daptomisien na hersamestelling met 10 ml natriumchloried 9 mg/ml (0,9 %) oplossing.
- Die ander bestanddeel is natriumhidroksied.

Hoe CUBACT lyk en inhoud van die pakkie
CUBACT poeier vir oplossing vir infusie word verskaf as 'n liggeel tot ligbruin, steriele gevriesdroogde poeier. Dit word gemeng met 'n oplosmiddel om 'n vloeistof te vorm voordat dit toegedien word.
Die aangemaakte oplossing is donkergeel tot ligbruin, sonder sigbare deeltjies.
CUBACT is verpak in 15 of 20 ml tipe I helder glasflessies met grys bromobutiel-rubberproppe, toegemaak met 'n aluminium/polipropileen-afwipseël. Beskikbaar in kartonne met 1 of 5 flessies. Nie alle verpakkingsgroottes word noodwendig bemark nie.

Houer van die registrasiesertifikaat
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Toegang tot die ooreenstemmende professionele inligting
Verwys asseblief na die SAHPRA-bewaarplek vir Professionele Inligting en Pasiëntinligtingsblaaie:
https://www.sahpra.org.za/pi-pil-repository/

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