FINAL PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

DABUCOR 350

DABUCOR 500

Powder for solution for injection/infusion

Daptomycin

Sugar free

Read all of this leaflet carefully before you are given DABUCOR

- 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 DABUCOR is and what it is used for

The active substance in DABUCOR powder for solution for injection or infusion is daptomycin.

Daptomycin is an antibacterial that can stop the growth of certain bacteria.

DABUCOR 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.

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DABUCOR 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 DABUCOR.

2. What you need to know before you are administered DABUCOR

DABUCOR should not be administered to you

If you are allergic to daptomycin or to sodium hydroxide or to any of the other ingredients of DABUCOR (listed in section 6).

Warnings and precautions

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

- If you have, or have previously had kidney problems. Your doctor may need to change the dose of DABUCOR.
- If you develop tender or aching muscles or muscle weakness. 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 DABUCOR. The symptoms generally go away within a few days of stopping DABUCOR.
- If you have ever developed a severe skin rash or skin peeling, blistering and/or mouth sores, or serious kidney problems after taking daptomycin.
- If you are very overweight. There is a possibility that your blood levels of DABUCOR could be higher than those found in persons of average weight and you may need careful monitoring in case of side effects.

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

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

- Serious, acute allergic reactions have been observed in patients treated with nearly all antibacterial agents, including DABUCOR. The symptoms can include wheezing, difficulty breathing, swelling of the face,

neck and throat, rashes and hives, or fever.

- Serious skin disorders have been reported with the use of DABUCOR. The symptoms that occur with these skin disorders can include:
    - a new or worsening fever,
    - red raised or fluid-filled skin spots which may start in your armpits or on your chest or groin areas and which can spread over a large area of your body,
    - blisters or sores in your mouth or on your genitals.
- A serious kidney problem has been reported with the use of DABUCOR. The symptoms can include fever and rash.
- 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.
- Diarrhoea, especially if you notice blood or mucus, or if diarrhoea becomes severe or persistent.
- 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 DABUCOR treatment.

DABUCOR 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 DABUCOR. Please inform your doctor that you are on treatment with DABUCOR.

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

Children and adolescents

DABUCOR should not be administered to children below 18 years of age as efficacy has not been established.

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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 DABUCOR

Tell your doctor or nurse if you are taking, have recently taken or might take any other medicines.

It is particularly important that you mention the following:

- Medicines called statins or fibrates (to lower cholesterol) or ciclosporin (a medicinal product 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 DABUCOR. Your doctor may decide not to give you DABUCOR 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 DABUCOR 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 breast-feeding

DABUCOR is not usually given to pregnant women. If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before you are given DABUCOR.

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.

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Driving and using machines

Adverse reactions such as headache, insomnia and dizziness have been reported, therefore if you experience these adverse reactions then you should not drive or use machines.

3. How to use DABUCOR

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

The dose will depend on how much you weigh and the type of infection being treated. DABUCOR will be 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 DABUCOR less often, e.g. once every other day. If you are receiving dialysis, and your next dose of DABUCOR is due on a dialysis day, you will be usually given DABUCOR after the dialysis session.

If you receive more DABUCOR than you should

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

If you forget to take DABUCOR

Since a healthcare professional will administer DABUCOR, it is unlikely that the dose will be missed.

4. Possible side effects

DABUCOR can have side effects.

Not all side effects for **DABUCOR** are included in this leaflet. Should your general health worsen or if you

experience any untoward effects while taking **DABUCOR,** please consult your doctor, pharmacist or other healthcare professional for advice.

If any of the following happens:

Serious side effects with frequency unknown

- A hypersensitivity reaction (serious allergic reaction including anaphylaxis and angioedema) has been reported, in some cases during administration of DABUCOR. 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 or hives,
- Swelling around throat,
- Rapid or weak pulse,
- Wheezing,
- Fever,
- Shivering or trembling,
- Hot flushes,
- Dizziness,
- Fainting,
- Metallic taste.
- Tell your doctor straight away if you experience unexplained muscle pain, tenderness, or weakness. Muscle problems can be serious, including muscle breakdown (rhabdomyolysis), which can result in kidney damage.

Other serious side effects that have been reported with the use of DABUCOR are

- A rare but potentially serious lung disorder called eosinophilic pneumonia, mostly after more than 2 weeks of treatment. The symptoms can include difficulty breathing, new or worsening cough, or new or worsening fever.

- Serious skin disorders. The symptoms can include:

- a new or worsening fever,

- red raised or fluid-filled skin spots which may start in your armpits or on your chest or groin areas and which can spread over a large area of your body,

- blisters or sores in your mouth or on your genitals.

- A serious kidney problem. The symptoms can include fever and rash.

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

The most frequently reported side effects are described below:

Frequent side effects

- Fungal infections such as thrush,

- Urinary tract infection,

- Decreased number of red blood cells (anaemia),

- Dizziness, anxiety, difficulty in sleeping,

- Headache,

- Fever, weakness (asthenia),

- High or low blood pressure,

- Constipation, abdominal pain,

- Diarrhoea, feeling sick (nausea) or being sick (vomiting),

- Flatulence,

- Abdominal swelling or bloating,

- Skin rash or itching,

- Pain, itchiness or redness at the site of infusion,

- Pain in arms or legs,

- Blood testing showing higher levels of liver enzymes or creatine phosphokinase (CPK).

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Other side effects which may occur following DABUCOR treatment is described below:

Less frequent side effects

- 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),
- Decreased appetite,
- Tingling or numbness of the hands or feet, taste disturbance,
- Trembling,
- Changes in heart rhythm, flushes,
- Indigestion (dyspepsia), inflammation of the tongue,
- Itchy rash of skin,
- Muscle pain, cramping, or weakness, inflammation of the muscles (myositis), joint pain,
- Kidney problems,
- Inflammation and irritation of the vagina,

General pain or weakness, tiredness (fatigue),

- Blood test showing increased levels of blood sugar, serum creatinine, myoglobin, or lactate dehydrogenase (LDH), prolonged blood clotting time or imbalance of salts,
- Itchy eyes.
- Yellowing of the skin and eyes,
- Prothrombin time prolonged.

Frequency unknown

Antibacterial-associated colitis, including pseudomembranous colitis (severe or persistent diarrhea containing blood and/or mucus, associated with abdominal pain or fever), easy bruising, bleeding gums, or nosebleeds.

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

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Reporting of side effects

If you get side effects, talk to your <doctor><or><,><pharmacist><or nurse>. This includes any possible side effects not listed in this leaflet. 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 DABUCOR.

5. How to store DABUCOR

- Store in a refrigerator (2 °C – 8 °C)
- Store all medicines out of reach of children.
- *After reconstitution*:

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

  Chemical and physical stability of the diluted solution in infusion bags is established as 12 hours at 25 °C or 24 hours at 2 °C – 8 °C.

6. Contents of the pack and other information

What DABUCOR contains

- The active substance is daptomycin.
- **DABUCOR 350**: One vial of powder contains 350 mg daptomycin. One ml provides 50 mg of daptomycin after reconstitution with 7 ml of sodium chloride 9 mg/ml (0.9 %) solution.
- **DABUCOR 500:** One vial of powder 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 ingredients are sodium hydroxide, water for injection and nitrogen.

What DABUCOR looks like and contents of the pack

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- **DABUCOR 350**: 20 ml clear lyo glass vial with 20 mm dark grey bromobutyl FM460 RFS lyo stopper and 20 mm flip off plain yellow seal.
- **DABUCOR 500:** 20 ml clear lyo glass vial with 20 mm dark grey bromobutyl FM460 RFS lyo stopper and 20 mm flip off plain royal blue seal.
- Pack size: 1 vial per carton.

HOLDER OF CERTIFICATE OF REGISTRATION

Accord Healthcare (Pty) Ltd

Building 2, Tuscany Office Park,

6 Coombe Place

Rivonia

Johannesburg

South Africa

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