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DR. REDDY'S LABORATORIES (PTY) LTD.
DRYMRED 500
PROPOSED CLEAN AMENDED PATIENT INFORMATION LEAFLET

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS S4

DRYMRED 500

Daptomycin 500 mg

Lyophilised powder for IV infusion

Sugar free

Read all of this leaflet carefully before you are given DRYMRED 500

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

What is in this leaflet

1. What DRYMRED 500 is and what it is used for

2. What you need to know before you use DRYMRED 500

3. How to use DRYMRED 500

4. Possible side effects

5. How to store DRYMRED 500

6. Contents of the pack and other information

1. What DRYMRED 500 is and what it is used for

Daptomycin belongs to the class of medicines known as antibiotics.

It works by stopping the growth of certain bacteria, thereby causing the death of the bacterial cells.

DRYMRED 500 is used in adults to treat certain complicated bacterial infections of the skin and the tissues below the skin, and to treat certain infections of the blood.

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2. What you need to know before you use DRYMRED 500

DRYMRED 500 should not be administered to you:

- if you are allergic (hypersensitive) to daptomycin or to any of the other ingredients of DRYMRED 500 (listed in section 6).

Warnings and precautions

Special care should be taken with DRYMRED 500:

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

- Serious, allergic reactions have been observed in patients treated with DRYMRED 500. Tell your doctor or nurse straight away if you experience the following symptoms suggestive of an allergic reaction: wheezing; difficulty breathing; swelling of the face, neck and throat; rashes and hives; fever.
- Diarrhoea, especially if you notice blood or mucus with abdominal pain and cramps, or if diarrhoea becomes severe or persistent. 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.
- 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 if you should continue the treatment.
- New or worsening fever, cough or difficulty breathing. These may be signs of a serious lung disorder called eosinophilic pneumonia. Your doctor will check the condition of your lungs and decide whether or not you should continue DRYMRED 500 treatment.
- If you develop 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. Tell your doctor if this happens. Your doctor will make sure you have a blood test and will advise you whether or not to continue with DRYMRED 500.

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Talk to your doctor or nurse before you are given DRYMRED 500:

- If you have, or have previously had kidney problems. Your doctor may need to adjust the dose of DRYMRED 500.
- If you are very overweight. There is a possibility that your blood levels of daptomycin (active substance in DRYMRED 500) could be higher than those found in patients 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 DRYMRED 500.

DRYMRED 500 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 DRYMRED 500. Please inform your doctor that you are on treatment with DRYMRED 500.

Your doctor will perform blood tests to monitor the health of your muscles both before you start treatment and frequently during treatment with DRYMRED 500.

Your doctor will check your progress closely while you are receiving DRYMRED 500. This will allow your doctor to see if the medicine is working properly and if you should continue to receive it. Check with your doctor if your symptoms do not improve within a few days or if they become worse.

Tell your doctor if you notice a new infection in addition to your existing infection (superinfection).

If you have a persistent or relapsing *Staphylococcus* infection, you should have repeated blood tests.

Children and adolescents

Do not give DRYMRED 500 to children and adolescents under the age of 18 as it is unlikely to be safe.

Other medicines and DRYMRED 500

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

Tell your doctor or nurse if you are taking any of the following:

- Medicines known to affect muscles, including medicines called statins used to lower cholesterol. It is possible that the risk of side-effects affecting the muscles may be higher when any of these medicines is taken during treatment with DRYMRED 500. While you are

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receiving DRYMRED 500, your doctor may decide 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), such as aspirin or ibuprofen or COX-2 inhibitors (e.g., celecoxib). These could interfere with the effects of DRYMRED 500 in the kidney.
- Warfarin (an oral anticoagulant), which is a medicine that prevents blood from clotting. Your doctor should monitor your blood clotting times while you are receiving DRYMRED 500 and warfarin.
- Tobramycin (an antibiotic).
- Laboratory test reagents for PT/INR testing.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before receiving DRYMRED 500.

The safe use of DRYMRED 500 during pregnancy and breastfeeding has not been determined.

Driving and using machines

DRYMRED 500 may cause dizziness or vertigo (a spinning sensation). You should not drive or use machines until it is established that your ability to perform such activities is not affected by DRYMRED 500.

3. How DRYMRED 500 will be administered

DRYMRED 500 will usually be given to you by a doctor or a nurse.

The dose will depend on how much you weigh and the type of infection being treated.

DRYMRED 500 is administered as an infusion lasting about 30 minutes.

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

If your kidneys do not work well, you may receive DRYMRED 500 less often, e.g., once every other day. If you are receiving dialysis, and your next dose of DRYMRED 500 is due on a dialysis day, you will be usually given DRYMRED 500 after the dialysis session.

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If you have the impression that the effect of DRYMRED 500 is too strong or too weak, tell your doctor or pharmacist.

If you receive more DRYMRED 500 than you should

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

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

If you miss a dose of DRYMRED 500

If you are concerned that you may have missed a dose of DRYMRED 500, talk to your doctor, pharmacist or nurse straight away.

4. Possible side-effects

DRYMRED 500 can have side-effects.

Not all side-effects reported for DRYMRED 500 are included in this leaflet. Should your general health worsen or if you experience any untoward effects while receiving DRYMRED 500, please consult your doctor, pharmacist or other healthcare professional for advice.

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

- A hypersensitivity reaction (very serious allergic reaction including anaphylaxis, angioedema, drug rash with eosinophilia and systemic symptoms (DRESS)) has been reported, in some cases during administration of DRYMRED 500. These very serious allergic reactions need immediate medical attention.

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

  - Chest pain or tightness
  - Shortness of breath, difficulty swallowing
  - Itching, hives, rash, rash with blistering
  - Swelling around throat
  - Rapid heartbeat, rapid or weak pulse
  - Wheezing

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- Fever
- Shivering or trembling
- Hot flushes
- Dizziness
- Fainting
- Metallic taste

- Severe or persistent watery diarrhoea or diarrhoea containing blood and/or mucus, associated with abdominal pain or fever (*Clostridium difficile*-associated diarrhoea).
- Tingling or numbness of the hands or feet, loss of feeling or difficulties with movements (peripheral neuropathy).
- Unexplained muscle pain, tenderness or weakness. Muscle problems can be serious, including muscle breakdown (rhabdomyolysis), which can result in kidney damage.
- Difficulty breathing, new or worsening cough, or new or worsening fever. If you experience these symptoms, you may have a potentially serious lung disorder called eosinophilic pneumonia. Eosinophilic pneumonia has been reported in patients given DRYMRED 500, mostly after more than 2 weeks of treatment.
- 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. You may need urgent medical attention or hospitalisation.

Tell your doctor or nurse immediately if you experience the following:

- Raised or fluid-filled skin spots 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 serious side-effects. You may need urgent medical attention.

Tell your doctor or nurse if you notice any of the following:

Frequent side-effects:

- Fungal infections such as thrush (white patches or sores in your mouth, vaginal itching or discharge).

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- Urinary tract infection.
- Bone infection.
- Decreased number of red blood cells (anaemia).
- Anxiety.
- Difficulty in sleeping.
- Dizziness.
- Headache.
- High or low blood pressure.
- Diarrhoea, feeling sick (nausea) or being sick (vomiting).
- Abdominal pains, flatulence, constipation, bloating.
- Pain, itchiness or redness at the site of infusion.
- Blood test showing higher levels of liver enzymes or creatine phosphokinase (CPK).
- Skin rashes.

Less frequent side-effects:

- Blood disorders (e.g., increased number of small blood particles called platelets which may increase the tendency for blood clotting, decreased number of platelets which may cause abnormal bleeding, or higher levels of certain types of white blood cells).
- Swollen, painful or tender lymph glands in the neck, armpit or groin.
- Decreased appetite.
- Increased levels of blood sugar, low levels of blood potassium, low levels of blood magnesium.
- Hallucination (seeing, hearing, or feeling things that are not there), mental changes.
- Difficulty with moving.
- Pricking, "pins and needles", or tingling feelings.
- Change in taste.
- Shaking (tremor).
- Irritated eyes, blurred vision.
- Ringing or buzzing or noise in the ears, feeling of constant movement of self or surroundings.

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- Changes in heart rhythm, stopping of heart.
- Flushes.
- Cough, shortness of breath.
- Abdominal swelling or bloating, constipation, abdominal pain, indigestion, flatulence, inflammation of the tongue, discomfort in upper, middle area of abdomen, sore mouth, sore gums, loose stools, dry mouth, oral numbness.
- Yellowing of the skin and eyes (jaundice).
- Skin rash or itching, hives.
- Joint pain, back pain, pain in arms or legs, muscle pain or weakness, muscle cramps, inflammation of the muscles (myositis).
- Kidney problems.
- Inflammation and irritation of the vagina.
- Fever, weakness (asthenia), chest pain, discomfort, general pain or weakness, tiredness (fatigue), swelling (oedema), shaking chills, feeling jittery.
- Pain at injection site.
- Protein in the urine (seen with laboratory test).
- Itchy eyes.
- Prothrombin time prolonged.
- Blood tests showing increased levels of blood creatinine, myoglobin, lactate dehydrogenase (LDH), liver enzymes, bicarbonate, phosphorus, prolonged blood clotting time or imbalance of salts.

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 or pharmacist or health care professional. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website.

By reporting side effects, you can help provide more information on the safety of DRYMRED 500.

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5. How to store DRYMRED 500

Store original packages in a refrigerator (2 to 8 °C). Avoid excessive heat.

After reconstitution/dilution: Although chemical and physical in-use stability for the reconstituted and diluted product has been demonstrated for 12 hours at 25 °C or 48 hours stored refrigerated 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 12 hours at 2 to 8 °C, unless reconstitution/dilution (etc) has taken place in controlled and validated aseptic conditions.

Do not freeze the reconstituted/diluted infusion solution.

Store all medicines out of reach of children

6. Contents of the pack and other information

What DRYMRED 500 contains

The active substance is daptomycin.

Each vial contains 500 mg daptomycin as sterile, lyophilised powder.

The other ingredient is: sodium hydroxide.

What DRYMRED 500 looks like and contents of the pack

A pale yellow to light brown lyophilised cake or powder.

When reconstituted: A pale yellow to light brown coloured, clear solution with no visible particles.

DRYMRED 500 powder for solution for infusion is filled in a clear 15 ml Type I glass vial sealed with a grey bromobutyl rubber stopper and an aluminium cap with a blue plastic flip-off seal, packed into cartons as single units.

Holder of Certificate of Registration

Dr. Reddy's Laboratories (Pty) Ltd.

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For any information about this medicine, please contact the local representative of the Holder of Certificate of Registration: Dr. Reddy's Laboratories (Pty) Ltd. Tel: +27 11 324 2100
Access to the corresponding Professional Information
Detailed information on this medicine is available on the Dr. Reddy's Laboratories (Pty) Ltd. website: http://www.drreddys.co.za

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