PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

EVEROLIMUS 2,5 DRL, Tablets

EVEROLIMUS 5 DRL, Tablets

EVEROLIMUS 10 DRL, Tablets

Everolimus

Contains lactose:

EVEROLIMUS 2,5 DRL: Each tablet contains 51,825 mg lactose.

EVEROLIMUS 5 DRL: Each tablet contains 103,65 mg lactose.

EVEROLIMUS 10 DRL: Each tablet contains 207,300 mg lactose.

Read all of this leaflet carefully before you start taking EVEROLIMUS DRL

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- EVEROLIMUS DRL has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. (see section 4)

What is in this leaflet

1. What EVEROLIMUS DRL is and what it is used for
2. What you need to know before you take EVEROLIMUS DRL
3. How to take EVEROLIMUS DRL
4. Possible side effects
5. How to store EVEROLIMUS DRL

6. Contents of the pack and other information

1. What EVEROLIMUS DRL is and what it is used for

EVEROLIMUS DRL is an anticancer medicine containing an active substance called everolimus.

Everolimus reduces the blood supply to the tumour and slows down the growth and spread of cancer cells.

EVEROLIMUS DRL is used to treat adult patients with:

- Advanced kidney cancer (advanced renal cell carcinoma), where other treatments (so-called "VEGF-targeted therapy") have not helped stop your disease.

2. What you need to know before you take EVEROLIMUS DRL

Do not take EVEROLIMUS DRL if:

- you are allergic to everolimus, to related substances such as sirolimus or temsirolimus, or to any of the other ingredients of this medicine (listed in section 6).
- you think you may be allergic, ask your doctor for advice.
- you are receiving live vaccines.
- you are pregnant or breastfeeding.

Warnings and precautions

Take special care with EVEROLIMUS DRL:

Tell your doctor, pharmacist, or healthcare provider if the following apply to you or the following complications occur due to EVEROLIMUS DRL treatment:

Talk to your doctor before taking EVEROLIMUS DRL:

- if you have any problems with your liver or if you have ever had any disease which may have affected your liver. If this is the case, your doctor may need to prescribe a different dose of EVEROLIMUS DRL.
- if you have diabetes (high level of sugar in your blood). EVEROLIMUS DRL may increase blood sugar levels and worsen diabetes mellitus. This may result in the need for insulin and/or oral antidiabetic agent therapy. Tell your doctor if you experience any excessive thirst or increased frequency of urination.
- if you are pregnant, think you may be pregnant, or if there is a chance that you might become pregnant

while on EVEROLIMUS DRL (see section 2 Pregnancy, breastfeeding and fertility).
• if you are breastfeeding (see section 2 Pregnancy, breastfeeding and fertility)
• if you need to receive a vaccine while taking EVEROLIMUS DRL.
• if you have high cholesterol. EVEROLIMUS DRL may elevate cholesterol and/or other blood fats.
• if you have had recent major surgery, or if you still have an unhealed wound following surgery. EVEROLIMUS DRL may increase the risk of problems with wound healing.
• if you have an infection. It may be necessary to treat your infection before starting EVEROLIMUS DRL. • if you have non-infectious pneumonitis (inflammation of the lung). • if you have pneumocystis jirovecii (carinii) pneumonia (PJP/PCP) (bacterial infection of the lung).
• if you have previously had hepatitis B, because this may be reactivated during treatment with EVEROLIMUS DRL (see section 4 Possible side effects).
• if you have received or are about to receive radiation therapy. • EVEROLIMUS DRL can cause complications of radiation therapy. Severe complications of radiotherapy (such as shortness of breath, nausea, diarrhoea, skin rashes and soreness in mouth, gums and throat), including fatal cases, have been observed in some patients who were taking everolimus at the same time as radiation therapy or who were taking everolimus shortly after they had radiation therapy. In addition, so-called radiation recall syndrome (comprising skin redness or lung inflammation at the site of previous radiation therapy) has been reported in patients who had radiation therapy in the past. Tell your doctor if you are planning to have radiation therapy in the near future, or if you have had radiation therapy before.
EVEROLIMUS DRL may also: • weaken your immune system. Therefore, you may be at risk of getting an infection while you are taking EVEROLIMUS DRL. If you have fever or other signs of an infection, consult with your doctor. Some infections may be severe and may have fatal consequences.
• impact your kidney function. Therefore, your doctor will monitor your kidney function while you are taking EVEROLIMUS DRL.
• cause shortness of breath, cough and fever.

- cause mouth ulcers and sores to develop. Your doctor might need to interrupt or discontinue your treatment with EVEROLIMUS DRL. You might need treatment with a mouthwash, gel or other products. Some mouthwashes and gels can make ulcers worse, so do not try anything without checking with your doctor first. Your doctor might restart treatment with EVEROLIMUS DRL at the same dose or at a lower dose.

Tell your doctor if you experience these symptoms.

You will have regular blood tests during treatment. These will check the amount of blood cells (white blood cells, red blood cells and platelets) in your body to see if EVEROLIMUS DRL is having an unwanted effect on these cells. Blood tests will also be carried out to check your kidney function (level of creatinine) and liver function (level of transaminases) and your blood sugar and cholesterol levels. This is because these can also be affected by EVEROLIMUS DRL.

Children and adolescents

EVEROLIMUS DRL is not to be used in children or adolescents.

Other medicines and EVEROLIMUS DRL

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines). The use of EVEROLIMUS DRL with these medicines may cause undesirable interactions.

Please consult your doctor, pharmacist or other health care professional for advice. Your doctor may need to change the dose of EVEROLIMUS DRL or the other medicines.

Tell your doctor if:

The following may increase the risk of side effects with EVEROLIMUS DRL:

- ketoconazole, itraconazole, voriconazole, or fluconazole and other antifungals used to treat fungal infections.
- clarithromycin, telithromycin or erythromycin, antibiotics used to treat bacterial infections.
- ritonavir and other medicines used to treat HIV infection/AIDS.
- verapamil or diltiazem, used to treat heart conditions or high blood pressure.
- dronedarone, a medicine used to help regulate your heart beat.
- ciclosporin, a medicine used to stop the body from rejecting organ transplants.

- imatinib, used to inhibit the growth of abnormal cells.
- angiotensin-converting enzyme (ACE) inhibitors (such as ramipril) used to treat high blood pressure or other cardiovascular problems.
- nefazodone, used to treat depression.
- aprepitant, a medicine used to prevent nausea and vomiting

The following may reduce the effectiveness of EVEROLIMUS DRL:

- rifampicin, used to treat tuberculosis (TB).
- efavirenz or nevirapine, used to treat HIV infection/AIDS.
- St. John's wort (*Hypericum perforatum*), a herbal product used to treat depression and other conditions.
- dexamethasone, a corticosteroid used to treat a wide variety of conditions including inflammatory or immune problems.
- phenytoin, carbamazepine or phenobarbital and other anti-epileptics used to stop seizures or fits.

These medicines should be avoided during your treatment with EVEROLIMUS DRL. If you are taking any of them, your doctor may switch you to a different medicine or may change your dose of EVEROLIMUS DRL.

EVEROLIMUS DRL with food and drink

Avoid grapefruit and grapefruit juice while you are on EVEROLIMUS DRL. It may increase the amount of EVEROLIMUS DRL in the blood, possibly to a harmful level.

Pregnancy, breastfeeding and fertility

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.

Pregnancy

You should not take EVEROLIMUS DRL during pregnancy.

Women who could potentially become pregnant should use highly effective contraception during treatment and for up to 8 weeks after ending treatment. If, despite these measures, you think you may have become pregnant, ask your doctor for advice **before** taking any more EVEROLIMUS DRL.

Breastfeeding

EVEROLIMUS DRL could harm your breastfed baby. You should not breastfeed during treatment and for 2

weeks after the last dose of EVEROLIMUS DRL. Tell your doctor if you are breastfeeding.

Female fertility

Absence of menstrual periods (amenorrhoea) has been observed in some female patients receiving EVEROLIMUS DRL. EVEROLIMUS DRL may have an impact on female fertility. Talk to your doctor if you wish to have children.

Male fertility

EVEROLIMUS DRL may affect male fertility. Talk to your doctor if you wish to father a child.

Driving and using machines

If you feel unusually tired (fatigue is a very common side effect), take special care when driving or using machines.

Important information about some of the ingredients of EVEROLIMUS DRL

EVEROLIMUS DRL contains lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. How to take EVEROLIMUS DRL

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

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The recommended dose is 10 mg, taken once a day. Your doctor will tell you how many tablets of EVEROLIMUS DRL to take.

If you have liver problems, your doctor may start you on a lower dose of EVEROLIMUS DRL.

If you experience certain side effects while you are taking EVEROLIMUS DRL (see section 4), your doctor may lower your dose or stop treatment, either for a short time or permanently.

Take EVEROLIMUS DRL once a day, at about the same time every day, consistently either with or without food.

Swallow the tablet(s) whole with a glass of water. Do not chew or crush the tablets.

If you take more EVEROLIMUS DRL than you should

In the event of EVEROLIMUS DRL overdosage, consult your doctor or pharmacist. If neither is available, contact

the nearest hospital or poison centre. Urgent treatment may be necessary.

Take the carton and this leaflet, so that the doctor knows what has been taken.

If you forget to take EVEROLIMUS DRL

If you miss a dose, take your next dose as scheduled. Do not take a double dose to make up for the forgotten tablets.

If you stop taking EVEROLIMUS DRL

Do not stop taking EVEROLIMUS DRL unless your doctor tells you to.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

EVEROLIMUS DRL can have side effects.

Not all side effects reported for EVEROLIMUS DRL are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking EVEROLIMUS DRL, please consult your doctor, pharmacist or health care provider for advice or go to the casualty department at your nearest hospital.

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

- Difficulty breathing or swallowing
- Swelling of the face, lips, tongue or throat
- Severe itching of the skin, with a red rash or raised bumps

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

Tell your doctor if you notice any of the following:

Frequent:

- Increased temperature, chills (signs of infection)
- Fever, coughing, difficulty breathing, wheezing (signs of inflammation of the lung, also known as pneumonitis)
- High level of sugar in the blood (hyperglycaemia)

• Loss of appetite
• Disturbed taste (dysgeusia)
• Headache
• Nose bleeds (epistaxis)
• Cough
• Mouth ulcers
• Upset stomach including feeling sick (nausea) or diarrhoea
• Skin rash
• Itching (pruritus)
• Feeling weak or tired
• Tiredness, breathlessness, dizziness, pale skin, signs of low level of red blood cells (anaemia)
• Swelling of arms, hands, feet, ankles or other part of the body (signs of oedema)
• Weight loss
• High level of lipids (fats) in the blood (hypercholesterolaemia)
• Excessive thirst, high urine output, increased appetite with weight loss, tiredness (signs of diabetes)
• Bleeding (haemorrhage), for example in the gut wall
• Severely decreased urine output (sign of kidney failure)
• Spontaneous bleeding or bruising (signs of low level of platelets, also known as thrombocytopenia)
• Breathlessness (dyspnoea)
• Thirst, low urine output, dark urine, dry flushed skin, irritability (signs of dehydration)
• Trouble sleeping (insomnia)
• Headache, dizziness (sign of high blood pressure, also known as hypertension)
• Fever, sore throat, mouth ulcers due to infections (signs of low level of white blood cells, leukopenia, lymphopenia and/or neutropenia)
• Fever
• Inflammation of the inner lining of the mouth, stomach, gut

• Dry mouth
• Heartburn (dyspepsia)
• Being sick (vomiting)
• Difficulty in swallowing (dysphagia)
• Abdominal pain
• Acne
• Rash and pain on the palms of your hands or soles of your feet (hand-foot syndrome)
• Reddening of the skin (erythema)
• Joint pain
• Pain in the mouth
• Menstruation disorders such as irregular periods
• High level of lipids (fats) in the blood (hyperlipidaemia, raised triglycerides)
• Low level of potassium in the blood (hypokalaemia)
• Low level of phosphate in the blood (hypophosphataemia)
• Low level of calcium in the blood (hypocalcaemia)
• Dry skin, skin exfoliation, skin lesions
• Nail disorders, breaking of your nails
• Mild loss of hair
• Abnormal results of liver blood tests (increased alanine and aspartate aminotransferase)
• Abnormal results of renal blood tests (increased creatinine)
• Swelling of the eyelid
• Protein in the urine
• Anxiety
• Somnolence (sleepiness)
Less frequent:
• Breathlessness, difficulty breathing when lying down, swelling of the feet or legs (signs of heart failure)

• Swelling and/or pain in one of the legs, usually in the calf, redness or warm skin in the affected area (signs of blockade of a blood vessel (vein) in the legs caused by blood clotting)
• Sudden onset of shortness of breath, chest pain or coughing up blood (potential signs of pulmonary embolism, a condition that occurs when one or more arteries in your lungs become blocked)
• Severely decreased urine output, swelling in the legs, feeling confused, pain in the back (signs of sudden kidney failure)
• Rash, itching, hives, difficulty breathing or swallowing, dizziness (signs of serious allergic reaction, also known as hypersensitivity)
• Weakness, spontaneous bleeding or bruising and frequent infections with signs such as fever, chills, sore throat or mouth ulcers (signs of low level of blood cells, also known as pancytopenia)
• Loss of sense of taste (ageusia)
• Coughing up blood (haemoptysis)
• Menstruation disorders such as absence of periods (amenorrhoea)
• Passing urine more often during daytime
• Heart pain
• Abnormal wound healing
• Hot flushes
• Discharge from the eye with itching and redness, pink eye or red eye (conjunctivitis)
• Shortness of breath or rapid breath (signs of acute respiratory distress syndrome)
• Tiredness, breathlessness, dizziness, pale skin (signs of low level of red blood cells, possibly due to a type of anaemia called pure red cell aplasia)
• Swelling of the face, around the eyes, mouth, and inside the mouth and/or throat, as well as the tongue and difficulty breathing or swallowing (also known as angioedema), may be signs of an allergic reaction
• Chest pain
Frequency unknown: • Reaction at the site of previous radiation therapy, e.g., skin redness or lung inflammation (so-called

radiation recall syndrome)

- Worsening of radiation treatment side effects

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 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 EVEROLIMUS DRL.

5. How to store EVEROLIMUS DRL

Store at or below 30 °C.

This medicine does not require any special storage conditions.

Do not store in a bathroom.

Do not dispose of medicines in drains or sewerage systems (e.g., toilets).

Do not use after the expiry date stated on the carton.

Store all medicines out of reach of children.

6. Contents of the pack and other information

What EVEROLIMUS DRL contains

The active substance is everolimus.

EVEROLIMUS 2,5 DRL: Each tablet contains 2,5 mg everolimus.

EVEROLIMUS 5 DRL: Each tablet contains 5 mg everolimus.

EVEROLIMUS 10 DRL: Each tablet contains 10 mg everolimus.

The other ingredients are butylated hydroxytoluene, crospovidone, hypromellose, lactose anhydrous, lactose monohydrate, magnesium stearate.

What EVEROLIMUS DRL looks like and contents of the pack

EVEROLIMUS 2,5 DRL: White to off-white with speckles, elongated tablets with bevelled edge, debossed with '1' on one side and plain on the other side.

EVEROLIMUS 5 DRL: White to off-white with speckles, elongated tablets with bevelled edge, debossed with '2' on one side and plain on the other side.

EVEROLIMUS 10 DRL: White to off-white with speckles, elongated tablets with bevelled edge, debossed with '4' on one side and plain on the other side.

EVEROLIMUS 2,5 / 5 / 10 DRL is packed in 30/60/90's:

- 10 tablets are sealed with cold formable foil and peelable lid foil blister pack comprised of cold formable Foil (with Dessicant and HDPE as sealent layer) and Aluminium paper backed peelable foil plain (sealable against PE).

Not all pack sizes may be marketed.

Holder of Certificate of Registration

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EVEROLIMUS 5 DRL: 56/32.16/1174

EVEROLIMUS 10 DRL: 56/32.16/1175

For any information about this medicine, please contact the local representative of the Holder of Certificate of Registration:

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Access to the corresponding Professional Information
Detailed information on this medicine is available on the Dr. Reddy's Laboratories (Pty) Ltd. web site: http://www.drreddys.co.za