Applicant/PHCR: DR REDDY'S LABORATORIES (PTY) LTD
Product proprietary name: LENALIDOMIDE DRL 5 / 10 / 15 / 25
Dosage form: Hard gelatin capsules
Strength: Each hard gelatin capsule contains lenalidomide 5/10/15/25 mg respectively

APPROVED PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

LENALIDOMIDE DRL 5, 5 mg, hard gelatin capsules

LENALIDOMIDE DRL 10, 10 mg, hard gelatin capsules

LENALIDOMIDE DRL 15, 15 mg, hard gelatin capsules

LENALIDOMIDE DRL 25, 25 mg, hard gelatin capsules

Lenalidomide

Contains sugar (mannitol)

LENALIDOMIDE DRL 5

Contains approximately 14 mg sugar (mannitol) per capsule.

LENALIDOMIDE DRL 10

Contains approximately 28 mg sugar (mannitol) per capsule.

LENALIDOMIDE DRL 15

Contains approximately 42 mg sugar (mannitol) per capsule.

LENALIDOMIDE DRL 25

Contains approximately 70 mg sugar (mannitol) per capsule.

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

- 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.
- LENALIDOMIDE 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.

WARNING: SEVERE LIFE-THREATENING HUMAN BIRTH DEFECTS.

Lenalidomide, the active ingredient contained in LENALIDOMIDE DRL, is structurally related to thalidomide, a substance that causes severe life-threatening birth defects. Lenalidomide showed malformations in monkeys, similar to those described with thalidomide (see section 2, 'Pregnancy and breastfeeding'). If LENALIDOMIDE DRL is taken during pregnancy, the same effect can be expected in humans.

BECAUSE OF THIS TOXIC EFFECT AND IN AN EFFORT TO MAKE THE CHANCE OF EXPOSURE DURING PREGNANCY TO LENALIDOMIDE DRL AS SMALL AS POSSIBLE, LENALIDOMIDE DRL IS APPROVED FOR USE UNDER A SPECIAL RESTRICTED DISTRIBUTION PROGRAMME. THIS PROGRAMME IS CALLED LEN PERM (PROGRAM FOR THE EVALUATION OF RISK AND MANAGEMENT).

What is in this leaflet

1. What LENALIDOMIDE DRL is and what it is used for
2. What you need to know before you take LENALIDOMIDE DRL
3. How to take LENALIDOMIDE DRL
4. Possible side effects
5. How to store LENALIDOMIDE DRL
6. Contents of the pack and other information

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

LENALIDOMIDE DRL belongs to a group of medicines called immunomodulatory medicines, which can modify or regulate the functioning of the immune system.

- LENALIDOMIDE DRL in combination with dexamethasone is used to treat adult patients who have previously received treatment for multiple myeloma. Multiple myeloma is a type of blood cancer that affects the white blood cells that produce

antibodies.

- LENALIDOMIDE DRL is also used to treat adult patients who have been diagnosed with myelodysplastic syndromes. Patients with myelodysplastic syndromes have an abnormality of their bone marrow, which means they don't make enough healthy blood cells.

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

Your doctor will have enrolled you in LEN PERM (PROGRAM FOR THE EVALUATION OF RISK AND MANAGEMENT) to ensure that LENALIDOMIDE DRL is used safely.

Do not take LENALIDOMIDE DRL

- if you are pregnant, think you may be pregnant or are planning to become pregnant, **as LENALIDOMIDE DRL is expected to be harmful to an unborn child** (see 'Pregnancy and breastfeeding').
- if you are able to become pregnant, unless you follow all the necessary measures to prevent yourself from becoming pregnant (see 'Pregnancy and breastfeeding'). If you are able to become pregnant, your doctor will record with each prescription that the necessary measures have been taken and provide you with this confirmation.
- If you are breastfeeding.
- if you are allergic (hypersensitive) to lenalidomide or any of the other ingredients of LENALIDOMIDE DRL listed in section 6. If you think you may be allergic, ask your doctor for advice.

If any of these apply to you, do not take LENALIDOMIDE DRL. Talk to your doctor if you are not sure.

Warnings and precautions

Take special care with LENALIDOMIDE DRL:

Please talk to your doctor in the following situations:

For women taking LENALIDOMIDE DRL

If you are able to become pregnant, even if you think this is unlikely, discuss this with your doctor before starting treatment.

If you are able to become pregnant:

- you will have pregnancy tests under the supervision of your doctor (before treatment, every 4 weeks during treatment, and 4 weeks after the treatment has finished) except in the case of confirmed tubal sterilisation
- and you must use two effective methods of contraception for 4 weeks before starting treatment, during treatment including dose interruptions and until 6 months after stopping treatment. Your doctor will advise you on appropriate methods of contraception.

For men taking LENALIDOMIDE DRL

LENALIDOMIDE DRL passes into human semen. If your female partner is pregnant or able to become pregnant, and she doesn't use effective contraception methods, you must use condoms during treatment including dose interruptions and for 3 months after the end of treatment (even if you have undergone vasectomy).

Female sexual partners (who can become pregnant) of male patients receiving LENALIDOMIDE DRL, should use highly effective contraception during their partner's treatment and for 6 months after their partner has stopped treatment with LENALIDOMIDE DRL.

Men should not father a child while receiving treatment with LENALIDOMIDE DRL. Men should use highly effective contraception while using LENALIDOMIDE DRL and for 3 months after stopping treatment with LENALIDOMIDE DRL.

Male patients taking LENALIDOMIDE DRL should not donate sperm or semen during treatment including dose interruptions and for 3 months following the end of treatment.

All patients

For males and females **with a permanent** non-childbearing potential, your prescriber will write a prescription for no more than a 12 weeks supply (3 months).

Talk to your doctor, pharmacist or nurse before taking LENALIDOMIDE DRL if:

- you have had blood clots in the past - you have an increased risk of developing blood clots in the veins and arteries during treatment
- you have any signs of an infection, such as a cough or fever
- you have or have ever had previous viral infection, particularly: hepatitis B infection, varicella zoster, HIV. If you are in doubt, talk to your doctor. Treatment with LENALIDOMIDE DRL may cause the virus to become active again, in patients who carry the virus. This results in a recurrence of the infection. Your doctor should check whether you have ever had hepatitis B infection
- you have kidney problems - your doctor may adjust your dose of LENALIDOMIDE DRL
- you have had a heart attack, have ever had a blood clot, or if you smoke, have high blood pressure or high cholesterol levels
- you have had an allergic reaction whilst taking thalidomide (another medicine used to treat multiple myeloma) such as rash, itching, swelling, dizziness or trouble breathing
- you have experienced in the past a combination of any of the following symptoms: widespread rash, red skin, high body temperature, flu-like symptoms, liver enzyme elevations, blood abnormalities (eosinophilia), enlarged lymph nodes – these are signs of a severe skin reaction called Drug Reaction with Eosinophilia and Systemic Symptoms which is also known as DRESS or drug hypersensitivity syndrome.

If any of the above apply to you, tell your doctor, pharmacist or nurse before starting treatment.

<u>At any time during or after your treatment, tell your doctor or nurse immediately if you:</u>

- experience blurred, loss of or double vision, difficulty speaking, weakness in an arm or a leg, a change in the way you walk or problems with your balance, persistent numbness, decreased sensation or loss of sensation, memory loss or confusion. These may all be symptoms of a serious and potentially fatal brain

condition known as progressive multifocal leukoencephalopathy (PML). If you had these symptoms prior to treatment with LENALIDOMIDE DRL, tell your doctor about any change in these symptoms

- experience shortness of breath, tiredness, dizziness, pain in the chest, a faster heartbeat, or swelling in the legs or ankles. These may be symptoms of a serious condition known as pulmonary hypertension (see section 4: 'Possible side effects').

Tests and checks

Before and during the treatment with LENALIDOMIDE DRL you will have regular blood tests as LENALIDOMIDE DRL may cause a drop in the blood cells that help fight infection (white blood cells) and help the blood to clot (platelets).

Your doctor may ask you to have a blood test:

If you have myelodysplastic syndrome:

- before treatment
- every week for the first 8 weeks of treatment
- at least every month after that.

If you have previously treated multiple myeloma:

- before treatment
- every 2 weeks for the first 12 weeks of treatment
- at least every month after that.

Your doctor may adjust your dose of LENALIDOMIDE DRL or stop your treatment based on the results of your blood tests and on your general condition. If you are newly diagnosed, your doctor may also assess your treatment based on your age and other conditions you already have.

LENALIDOMIDE DRL may lower the number of blood platelets in your body. Because of this, you may bleed more easily. Tell your doctor if you have any signs of bleeding, such as nosebleeds.

Your doctor may check if you have a high total amount of tumour throughout the body,

including your bone marrow. This could lead to a condition where the tumours break down and cause unusual levels of chemicals in the blood which can lead to kidney failure (this condition is called 'Tumour Lysis Syndrome').

Serious skin reactions can occur with LENALIDOMIDE DRL. Check with your doctor right away if you have blistering, peeling, or loosening of the skin, skin rash, or fever or chills while you are using LENALIDOMIDE DRL.

Your doctor may check you for changes to your skin such as red spots or rashes.

Your doctor may monitor your thyroid function.

Serious liver problems can occur with LENALIDOMIDE DRL. Your doctor may order blood tests to monitor your liver.

Regular monitoring of vision is recommended, since cataract has been reported in patients receiving LENALIDOMIDE DRL.

You should not donate blood during treatment including dose interruptions and for 3 months after the end of treatment.

You should never give LENALIDOMIDE DRL to another person. Return any unused capsules to your pharmacist at the end of treatment.

Children and adolescents

LENALIDOMIDE DRL is not recommended for use in children and adolescents under 18 years.

Elderly and people with kidney problems

If you are elderly or have moderate to severe kidney problems - your doctor will check you carefully before starting treatment.

Other medicines and LENALIDOMIDE DRL

Always tell your health care provider if you are taking any other medicine.

(This includes complementary or traditional medicines.)

Inform your doctor if you take:

- Warfarin (medicine to prevent blood clotting);
- Digoxin (medicine used to treat heart problems);

- Statins (medicines used to treat high cholesterol);
- Medicines that stimulate the production of red blood cells, or other medicines that may increase the risk of blood clots (thrombosis), such as hormone replacement therapy;
- Medicines used to prevent pregnancy such as oral contraceptives, as they may stop working.

Taking LENALIDOMIDE DRL with food and drink

The LENALIDOMIDE DRL capsules can be taken either with or without food (see following section: 'How to take LENALIDOMIDE DRL').

Pregnancy and breastfeeding

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 receiving this medicine.

Pregnancy:

You must not take LENALIDOMIDE DRL if you are pregnant, as it is expected to be harmful for an unborn baby. In addition, you must not become pregnant while taking LENALIDOMIDE DRL.

Therefore, you must use two effective methods of contraception if you are a woman of childbearing potential (see section: 'Take special care with LENALIDOMIDE DRL').

If you do become pregnant during the treatment with LENALIDOMIDE DRL, you must stop the treatment and inform your doctor immediately.

For men taking LENALIDOMIDE DRL, please see section: 'Take special care with LENALIDOMIDE DRL'. If your partner becomes pregnant whilst you are taking LENALIDOMIDE DRL, you should inform your doctor immediately. It is recommended that your partner seeks medical advice. You must also use effective methods of contraception (see section: 'Take special care with LENALIDOMIDE DRL').

Breastfeeding:

You must not breastfeed when taking LENALIDOMIDE DRL, as it is not known if

LENALIDOMIDE DRL passes into breast milk.

Driving and using machines

Do not drive or operate machines if you feel dizzy, tired, sleepy, have vertigo or blurred vision after taking LENALIDOMIDE DRL.

3. How to take LENALIDOMIDE DRL

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

LENALIDOMIDE DRL is taken alone or in combination with dexamethasone. Always take LENALIDOMIDE DRL alone or LENALIDOMIDE DRL and dexamethasone in combination exactly as your doctor has told you.

Check with your doctor or pharmacist if you are not sure.

You should refer to the patient information leaflet for dexamethasone for further information on its use and effects.

Your doctor will prescribe the correct dose for your condition.

Your doctor may adjust your dose of LENALIDOMIDE DRL or stop your treatment based on the results of your blood tests and on your general condition (see section: 'Take special care with LENALIDOMIDE DRL').

You should swallow the LENALIDOMIDE DRL capsules whole, preferably with water, once a day. Do not break, open or chew the capsules. The LENALIDOMIDE DRL capsules can be taken either with or without food.

You should take LENALIDOMIDE DRL at about the same time each day.

Do not open or crush the hard gelatin capsules. If powder from lenalidomide makes contact with your skin, wash your skin immediately and thoroughly with soap and water. If lenalidomide makes contact with your mucous membranes (a lubricating membrane lining body cavities such as the nose and mouth), they should be thoroughly flushed with water.

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

Duration of the treatment with LENALIDOMIDE DRL

LENALIDOMIDE DRL is taken in treatment cycles, each cycle lasting 28 days. You should continue the cycles of treatment until your doctor tells you to stop.

If you take more LENALIDOMIDE DRL than you should

If you take more LENALIDOMIDE DRL than was prescribed, tell your doctor immediately. In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

If you forget to take LENALIDOMIDE DRL

If less than 12 hours has elapsed since missing a dose, you can take the dose. If more than 12 hours has elapsed since missing a dose at the normal time, you should not take the dose, but take the next dose at the normal time on the following day. Do not take 2 doses at the same time.

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

4. Possible side effects

LENALIDOMIDE DRL can have side effects.

Not all side effects reported for LENALIDOMIDE DRL are included in this leaflet. Should your general health worsen or if you experience any untoward effects while receiving LENALIDOMIDE DRL, please consult your health care provider for advice.

It is important to note that LENALIDOMIDE DRL may reduce the number of white blood cells that fight infection and also the blood cells which help the blood to clot (platelets) which may lead to bleeding disorders such as nosebleeds and bruising.

LENALIDOMIDE DRL may also cause blood clots in the veins (thrombosis).

Therefore, **you must tell your doctor immediately** if you experience:

- Fever, chills, sore throat, cough, mouth ulcers or any other symptoms of infection including within the bloodstream (sepsis)

- Bleeding or bruising in the absence of injury
- Chest pain or leg pain
- Shortness of breath

These are all serious side effects. You may need urgent medical attention.

If any of the following symptoms occur, it may be a serious allergic reaction. Stop taking LENALIDOMIDE DRL and tell your doctor immediately or go to the casualty department at your nearest hospital. You may need urgent medical attention or hospitalisation:

- An allergic reaction which may begin as rash in one area but spread with extensive loss of skin over the whole body.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- Wheezing, shortness of breath or a dry cough, which may be symptoms caused by inflammation of the tissue in the lungs, may occur.

These are all serious side effects. You may need urgent medical attention.

Other side effects

It is important to note that patients with multiple myeloma may develop additional types of cancer, and it is possible that this risk may be increased with LENALIDOMIDE DRL treatment.

<u>Frequent side effects:</u>

- A drop in the number of white blood cells (the cells that fight infection), platelets (the cells that help the blood to clot, which may lead to bleeding disorders) and red blood cells (anaemia leading to tiredness and weakness).
- Constipation, diarrhoea, nausea, redness of skin, rashes, vomiting, muscle cramps, muscle weakness, muscle pain, muscle aches, bone pain, joint pain, back pain, pain in the extremities, tiredness, generalised swelling including swelling of your arms and legs
- Fever and flu like symptoms including fever, cough, muscle ache, headache and chills

- Numbness, tingling or burning sensation to the skin, pains in hands or feet, dizziness, tremor, changes in the way things taste
- Chest pain spreading to the arms, neck, jaw, back or stomach, feeling sweaty and breathless, feeling sick or vomiting, which may be symptoms of a heart attack (myocardial infarction)
- Decreased appetite, low levels of potassium in the blood
- Leg pain (which could be a symptom of blood clots (thrombosis)), chest pain or shortness of breath (which may be a symptom of blood clots in the lungs, called pulmonary embolism)
- Chest pain
- Difficulty breathing
- Infections of any types
- Infection of the lung and the upper respiratory tract, shortness of breath
- Blurred vision
- Clouding of your eye (cataract)
- Reduced vision
- Kidney problems
- Increase in liver test results
- Increases in your blood sugar level (diabetes)
- Headache
- Stomach pain
- Mood change
- Increased blood pressure or a drop in blood pressure, slow, fast or irregular heart beat
- Sore inflamed mouth, dry mouth
- Infection of the sinuses that surround the nose
- Bleeding from the gums, stomach, or bowels, bruising, nosebleed

- Skin eruptions, skin cracking, flaking or peeling skin
- Hives, itching, dry skin, increased sweating, dehydration
- Heartburn
- Production of much more or much less urine than usual (which may be a symptom of kidney failure)
- Shortness of breath especially when lying down (which may be a symptom of heart failure)
- Stroke, fainting
- Joint swelling
- Low levels of calcium, phosphate or magnesium in the blood
- Abdominal pain
- Depression
- Abnormal liver test results
- An excess of iron in the body
- Thirst
- Toothache
- Weight loss

Less frequent side effects:

- Hives, rashes, swelling of eyes, mouth or face, difficulty breathing, or itching, which may be symptoms of an allergic reaction
- Increase in blood pressure within blood vessels that supply the lungs (pulmonary hypertension).

Frequency unknown:

- Serious allergic reaction that may begin as a rash in one area but spread with extensive loss of skin over the whole body (Stevens-Johnson syndrome and/or toxic epidermal necrolysis).
- Tumour lysis syndrome - metabolic complications that can occur during treatment

of cancer and sometimes even without treatment. These complications are caused by the break-down products of dying cancer cells and may include the following: changes to blood chemistry - high potassium, phosphorus, uric acid, and low calcium consequently leading to changes in kidney function, heart beat, seizures, and sometimes death.

- Increase in pain, tumour size, redness around the tumour
- Wheezing, shortness of breath or a dry cough, which may be symptoms caused by inflammation of the tissue in the lungs.

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 LENALIDOMIDE DRL.

5. How to store LENALIDOMIDE DRL

Store all medicines out of reach of children.

- Store at or below 25 ºC
- Keep the container in the outer carton
- Keep the container tightly closed
- Do not remove the blisters from the carton until required for use
- Do not use LENALIDOMIDE DRL after the expiry date which is stated on the label and carton.
- 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 LENALIDOMIDE DRL contains

- The active substance is lenalidomide.

LENALIDOMIDE DRL 5

Each hard gelatin capsule contains lenalidomide 5 mg.

LENALIDOMIDE DRL 10

Each hard gelatin capsule contains lenalidomide 10 mg.

LENALIDOMIDE DRL 15

Each hard gelatin capsule contains lenalidomide 15 mg.

LENALIDOMIDE DRL 25

Each hard gelatin capsule contains lenalidomide 25 mg.

- The other ingredients are:

  Capsule contents: Croscarmellose sodium, magnesium stearate, mannitol, microcrystalline cellulose and povidone

  Capsule shell: Gelatin, Sodium lauryl sulphate, titanium dioxide (E171), FD & C blue 2 (E132) (LENALIDOMIDE DRL 10, LENALIDOMIDE DRL 15), Iron oxide yellow (LENALIDOMIDE DRL 10)

  Printing ink: Black iron oxide, potassium hydroxide, propylene glycol and shellac

What LENALIDOMIDE DRL looks like and contents of the pack

LENALIDOMIDE DRL 5

White to off-white coloured powder filled in size '4' hard gelatin capsules with opaque white coloured cap imprinted 'RDY' with black ink and opaque white colored body imprinted '5 mg' with black ink.

LENALIDOMIDE DRL 10

White to off-white coloured powder filled in size '2' hard gelatin capsules with pale green

coloured cap imprinted 'RDY' with black ink and pale yellow coloured body imprinted '10 mg' with black ink.

LENALIDOMIDE DRL 15

White to off-white coloured powder filled in size '1' hard gelatin capsules with blue coloured cap imprinted 'RDY' with black ink and white coloured body imprinted '15 mg' with black ink.

LENALIDOMIDE DRL 25

White to off-white coloured powder filled in size '0' hard gelatin capsules with opaque white coloured cap imprinted 'RDY' with black ink and opaque white coloured body imprinted '25 mg' with black ink.

HDPE containers

The hard gelatin capsules are packed in white HDPE containers stoppered with white, plastic, child resistant caps, with a modified RH 20 % silica gel 1 g sachet cutform. The HDPE containers are packed into a cardboard unit carton.

LENALIDOMIDE DRL 15 / LENALIDOMIDE DRL 25

Pack size of 21 hard gelatin capsules.

LENALIDOMIDE DRL 5 / LENALIDOMIDE DRL 10

Pack size of 28 hard gelatin capsules.

Blister packs

Blister packs of 7 hard gelatin capsules (1 blister strip of 7 hard gelatin capsules each), 14 hard gelatin capsules (2 blister strips of 7 hard gelatin capsules each), 21 hard gelatin capsules (3 blister strips of 7 hard gelatin capsules each), or 28 hard gelatin capsules (4 blister strips of 7 hard gelatin capsules each) are available.

The hard gelatin capsules are packed into aluminium / aluminium foil blister strips composed of aluminium foil with heat seal laquer and cold formable aluminium foil. Each blister strip contains 7 hard gelatin capsules. The blister strip/s are packed into a cardboard unit carton.

Not all pack sizes may be marketed.

Holder of Certificate of Registration

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LENALIDOMIDE DRL 5: 52/26/0791

LENALIDOMIDE DRL 10: 52/26/0792

LENALIDOMIDE DRL 15: 52/26/0793

LENALIDOMIDE DRL 25: 52/26/0794

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

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

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