Module 1.3.2: Patient Information Leaflet for

LENALIDOMIDE CIPLA 5, 10, 15, 25 (Capsules)

SCHEDULING STATUS

S4

LENALIDOMIDE CIPLA 5 mg/10 mg/ 15 mg/ 25 mg hard gelatin capsules

Lenalidomide

Contains sugar (147 mg anhydrous lactose for lenalidomide 5 mg)

Contains sugar (294 mg anhydrous lactose for lenalidomide 10 mg)

Contains sugar (120 mg anhydrous lactose for lenalidomide 15 mg)

Contains sugar (200 mg anhydrous lactose for lenalidomide 25 mg)

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

- 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 CIPLA 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 CIPLA, is structurally related to thalidomide, a medicine that causes severe life-threatening birth defects. Lenalidomide showed malformations in monkeys, similar to those described with thalidomide (see '**Pregnancy and lactation**'). If LENALIDOMIDE CIPLA 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 CIPLA AS SMALL AS POSSIBLE, LENALIDOMIDE CIPLA IS APPROVED FOR USE UNDER A SPECIAL RESTRICTED DISTRIBUTION PROGRAMME.

UNDER THE RESTRICTED DISTRIBUTION RISK MANAGEMENT PROGRAMME, ONLY DOCTORS REGISTERED WITH THE PROGRAMME ARE ALLOWED TO PRESCRIBE THE PRODUCT AND PHARMACISTS REGISTERED WITH THE PROGRAMME ARE ALLOWED TO DISPENSE THE PRODUCT. IN ADDITION, YOU MUST BE ADVISED OF, AGREE TO, AND COMPLY WITH THE REQUIREMENTS OF RESTRICTED DISTRIBUTION RISK MANAGEMENT PROGRAM.

What is in this leaflet:

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

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

What LENALIDOMIDE CIPLA is

LENALIDOMIDE CIPLA contains the active substance, lenalidomide 5 mg, 10 mg, 15 mg, and 25 mg. This medicine belongs to a group of medicines called immunomodulators, which regulate how your immune system works.

What LENALIDOMIDE CIPLA is used for

LENALIDOMIDE CIPLA is used in adults for:

- Myelodysplastic syndromes

- Multiple myeloma

Myelodysplastic syndromes (MDS)

MDS are a collection of many different blood and bone marrow diseases. Patients with MDS have an abnormality of their bone marrow, which means they do not make enough healthy blood cells. Patients can experience a variety of signs and symptoms including a low red blood cell count (anaemia), the need for a blood transfusion, and be at risk of infection.

LENALIDOMIDE CIPLA is used alone to treat adult patients who have been diagnosed with MDS, when all of the following apply:

- you need regular blood transfusions to treat low levels of red blood cells ('transfusion-dependent anaemia')
- you have an abnormality of cells in the bone marrow called an 'isolated deletion 5q cytogenetic abnormality'. This means your body does not make enough healthy blood cells

LENALIDOMIDE CIPLA can increase the number of healthy red blood cells that the body produces by reducing the number of abnormal cells:

this can reduce the number of blood transfusions needed. It is possible that no transfusions will be needed.

Multiple myeloma

Multiple myeloma is a type of cancer which affects a certain kind of white blood cell, called the plasma cell. These cells collect in the bone marrow and divide, becoming out of control. This can damage the bones and kidneys.

Multiple myeloma generally cannot be cured. However, the signs and symptoms can be greatly reduced or disappear for a period of time. This is called a 'response'.

LENALIDOMIDE CIPLA, in combination with an anti-inflammatory medicine called 'dexamethasone', is used to stop the signs and symptoms of multiple myeloma getting worse. It has also been shown to delay multiple myeloma from coming back following treatment.

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

Follow all of your doctor's instructions carefully, even if they differ from the general information given in this leaflet.

Your doctor will have enrolled you in the RISK MANAGEMENT PROGRAM to ensure that LENALIDOMIDE CIPLA is used safely.

Do not take LENALIDOMIDE CIPLA if:

- You are allergic to lenalidomide or any of the excipients **(see "what LENALIDOMIDE CIPLA contains")**
- You are pregnant, think you may be pregnant or are planning to become pregnant or breast-feeding **(see "Pregnancy and lactation").**
- You are able to become pregnant, unless you follow all the necessary measures to prevent you from becoming pregnant.

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

Warnings and precautions

For women taking LENALIDOMIDE CIPLA

Before starting the treatment, you should ask your doctor if you are able to become pregnant, even if you think this is unlikely.

You must not take LENALIDOMIDE CIPLA if you are pregnant, as it is expected to be harmful to an unborn baby **(see "Do not take LENALIDOMIDE CIPLA")**.

You must not become pregnant while taking LENALIDOMIDE CIPLA. Therefore, you must use effective methods of contraception if you are a woman of childbearing potential **(see "Do not take LENALIDOMIDE CIPLA")**.

If you can 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 4 weeks after stopping treatment. Your doctor will advise you on appropriate methods of contraception.

For men taking LENALIDOMIDE CIPLA

If your partner becomes pregnant whilst you are taking LENALIDOMIDE CIPLA, you should inform your doctor immediately. It is recommended that your partner seeks medical advice.

LENALIDOMIDE CIPLA passes into human semen. If your female partner is pregnant or able to become pregnant, and she doesn't use effective methods of contraception, you must use condoms during treatment including dose interruptions and for 4 weeks after the end of treatment (even if you have undergone vasectomy).

Male patients taking LENALIDOMIDE CIPLA should not donate sperm or semen during treatment including dose interruptions and for 4 weeks following the end of treatment.

All patients

Talk to your doctor, pharmacist, or nurse before taking LENALIDOMIDE CIPLA 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 zona, HIV. If you are in doubt, talk to your doctor. Treatment with LENALIDOMIDE CIPLA may cause virus to become active again, in patients who carry the virus, resulting 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 CIPLA
- 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 heart or lung disease, as treatment with LENALIDOMIDE CIPLA may cause life threatening high blood pressure of the arteries in your lungs and heart. Your doctor will evaluate you before and during treatment for any signs and symptoms of heart or lung disease.
- 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: rash on face or extended rash, red skin, high fever, flu-like symptoms, enlarged lymph nodes (signs of severe skin reaction called drug reaction with eosinophilia and Systemic Symptoms (DRESS) **(see "Possible side effects")**

If you have MDS, you may be more likely to get a more advanced condition called acute myeloid leukaemia (AML). In addition, it is not known how LENALIDOMIDE CIPLA affects the chances of you getting AML. Your doctor may therefore do tests to check for signs which may better predict the likelihood of you getting AML during your treatment with LENALIDOMIDE CIPLA**.**

Before and during the treatment with LENALIDOMIDE CIPLA, you will have regular blood tests as LENALIDOMIDE CIPLA may cause a fall in the blood cells that help fight infection and help the blood to clot. Your doctor may ask you to have a blood test:

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

Your doctor may check if you have a high total amount of tumours 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’).

Your doctor may check you for changes to your skin such as red spots or rashes.
Your doctor may adjust your dose of LENALIDOMIDE CIPLA 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
Before you start treatment, you should tell your doctor if you have kidney disease. Your doctor may adjust your dose of LENALIDOMIDE CIPLA based on this information.

Blood donation

You should not donate blood during treatment including dose interruptions and for 4 weeks after the end of treatment.

Children and adolescents

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

Elderly and people with kidney problems

If you are aged 65 years or older or have moderate to severe kidney problems - your doctor will check you.

Other medicines and LENALIDOMIDE CIPLA

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

Inform your doctor if you take:

- Warfarin (medicine to prevent blood clotting)
- Digoxin (medicine used to treat heart problems)
- Medicines that stimulate the production of red blood cells, or other agents that may increase the risk of blood clots (thrombosis), such as hormone replacement therapy
- Some medicines used to treat asthma – dexamethasone
- Some medicines used treat cholesterol - statins

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

Women taking LENALIDOMIDE CIPLA

You must not take LENALIDOMIDE CIPLA if you are pregnant, as it is expected to be harmful to an unborn baby **(see "Do not take LENALIDOMIDE CIPLA)**.

You must not become pregnant while taking LENALIDOMIDE CIPLA Therefore, you must use effective methods of contraception if you are a woman of childbearing potential **(see "Do not take LENALIDOMIDE CIPLA")**.

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

Men taking LENALIDOMIDE CIPLA

If your partner becomes pregnant whilst you are taking LENALIDOMIDE CIPLA, you should inform your doctor immediately. It is recommended that your partner seeks medical advice.

LENALIDOMIDE CIPLA passes into human semen. If your female partner is pregnant or able to become pregnant, and she does not use effective methods of contraception, you must use condoms during treatment and 4 weeks after the end of treatment, even if you have had a vasectomy.

Breastfeeding.

You should not breastfeed when taking LENALIDOMIDE CIPLA.

Driving and using machines

LENALIDOMIDE CIPLA may affect the ability to drive and use machines. Do not drive or operate machines if you experience side effects such as dizziness, tiredness, sleepiness, or blurred vision after taking LENALIDOMIDE CIPLA.

LENALIDOMIDE CIPLA contains sugar in the form of anhydrous lactose

Tell your doctor or healthcare professional if you are allergic or have intolerant to some sugars so that alternate therapy may be recommended.

3. How to take LENALIDOMIDE CIPLA

LENALIDOMIDE CIPLA must be given to you by healthcare professionals with experience in treating multiple myeloma or MDS.

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

If you are taking LENALIDOMIDE CIPLA in combination with other medicines, you should refer to the package leaflets for these medicines for further information on their use and effects.

Treatment cycle

LENALIDOMIDE CIPLA is taken on certain days over 4 weeks (28 days).

- Each 28 days is called a ‘treatment cycle’.
- Depending on the day of the cycle, you will take one or more of the medicines. However, on some days you do not take any of the medicines.
- After completing each 28-day cycle, you should start a new ‘cycle’ over the next 28 days.

How much LENALIDOMIDE CIPLA to take

Before you start treatment, your doctor will tell you:

- how much LENALIDOMIDE CIPLA you should take
- how much of the other medicines you should take in combination with LENALIDOMIDE CIPLA, if any.
- on what days of your treatment cycle to take each medicine.

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

LENALIDOMIDE CIPLA is taken alone or in combination with dexamethasone. Always take LENALIDOMIDE CIPLA alone or LENALIDOMIDE CIPLA and dexamethasone in combination exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure. You should refer to the package 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 CIPLA or stop your treatment based on the results of your blood tests and on your general condition (see Section: ‘**Take special care with LENALIDOMIDE CIPLA’**).

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

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

If you have the impression that the effect of LENALIDOMIDE CIPLA is too strong or too weak, talk to your doctor

Taking LENALIDOMIDE CIPLA with food and drink

LENALIDOMIDE CIPLA can be administered with or without food, preferably with water.

Duration of the treatment with LENALIDOMIDE CIPLA

LENALIDOMIDE CIPLA 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 CIPLA than you should

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

If you forget to take LENALIDOMIDE CIPLA

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.

4. Possible side effects

LENALIDOMIDE CIPLA can have side effects.

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

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

- any fever, chills, sore throat, cough, mouth ulcers or any other symptoms of infection.
- any bleeding or bruising in the absence of injury
- any chest or leg pain.
- any shortness of breath.
- bone pain, muscle weakness, confusion or tiredness that might be due to high level of calcium in the blood (hypercalcaemia).

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 CIPLA treatment, therefore your doctor should carefully evaluate the benefit and risk when you are prescribed LENALIDOMIDE CIPLA.

If any of the following symptoms occur, it may be a serious allergic reaction. Stop taking LENALIDOMIDE CIPLA 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.

Frequent side effects are given below. You should consult your doctor if you experience any of these:

- A fall 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 aches, bone pain, joint pain, tiredness, generalised swelling including swelling of the limbs.
- Fever and flu like symptoms including fever, muscle ache, headache, and chills.
- Numbness, tingling or burning sensation to the skin, pains in hands or feet, dizziness, tremor, taste disturbance.
- 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).
- Infection of the lung and the upper respiratory tract, shortness of breath, nosebleed.
- Blurred vision.
- Headache.
- Chest pain.
- Difficulty breathing.
- Shortness of breath, dizziness, fatigue, and chest pain, as this may be due to high blood pressure affecting the arteries in the lungs and heart.
- Infections of all types.
- Infection of the sinuses that surround the nose.
- Bleeding from the gums, stomach, or bowels, bruising.
- Increased blood pressure or a fall in blood pressure, slow, fast, or irregular heartbeat.
- Skin eruptions, skin cracking, flaking.
- Hives, itching, dry skin, increased sweating, dehydration.

- Sore inflamed mouth, dry mouth.
- Abdominal pain.
- 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).
- Difficulty in obtaining an erection.
- 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).
- Stroke, fainting.
- Muscle weakness.
- Joint swelling.
- Low levels of calcium, phosphate, or magnesium in the blood.
- Depression.
- Cataract.
- Reduced vision.
- Abnormal liver test results.
- Iron overload.
- Mood change.
- Toothache.

Less frequent side effects are given below. You should consult your doctor if you experience any of these:

- Bleeding in the brain.
- Circulatory problems.
- Certain types of cancer of the skin

- Hypersensitivity or an allergic reaction (angioedema), a type of allergic reaction that may have symptoms such as hives, rashes, swelling of eyes, mouth or face, difficulty of breathing, or itching.
- Tumour lysis syndrome - metabolic complications that can occur during treatment of cancer and sometimes even without treatment.

Side effects where the frequency is not known are given below. You should consult your doctor if you experience any of these:

- Sudden, or mild but worsening pain in the upper abdomen and/or back, which remains for a few days, possibly accompanied by nausea, vomiting, fever and a rapid pulse − these symptoms may be due to inflammation of the pancreas.

Reporting of side effects

If you get side effects, talk to your doctor 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 or drugsafetysa@cipla.com. By reporting side effects, you can help provide more information on the safety of LENALIDOMIDE CIPLA.

5. How to store LENALIDOMIDE CIPLA

Store all medicines out of reach of children.

Store at or below 25 °C.

Keep in the outer carton until required for use

Do not use after the expiry date stated on the label / 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 CIPLA contains

The active substance is: Lenalidomide

The other ingredients are:

Anhydrous lactose (Duralac H)

Croscarmellose sodium (AC-DI-SOL)

Magnesium stearate (vegetable grade)

Microcrystalline cellulose (Avicel PH 102)

Hard gelatin capsule:

The composition of empty hard gelatin capsule are:

Gelatin

Titanium dioxide (E171)

Yellow iron oxide (E172) for 10 mg ONLY

Indigotine FD&C Blue #2 (E132) for 10 mg & 15 mg ONLY

Composition of ink used for printing on Capsule Shella are:

Shellac - E904

Propylene glycol – E1520

Strong ammonia solution – E527

Black iron oxide – E172

Potassium hydroxide – E525

What LENALIDOMIDE CIPLA looks like and contents of the pack

LENALIDOMIDE CIPLA 5: White to off white powder filled in size ‘2’ hard gelatin white and white capsule spin printed in black ink with ‘Cipla 5 mg’ on the cap.

LENALIDOMIDE CIPLA 10: White to off white powder filled in size ‘0’ hard gelatin blue green and pale-yellow capsule spin printed in black ink with ‘Cipla 10 mg’ on the cap.

LENALIDOMIDE CIPLA 15: White to off white powder filled in size '0' hard gelatin pale blue and white capsule spin printed in black ink with 'Cipla 15 mg' on the cap.

LENALIDOMIDE CIPLA 25: White to off white powder filled in size '0' hard gelatin white and white capsule spin printed in black ink with 'Cipla 25 mg' on the cap.

LENALIDOMIDE CIPLA capsules 5 mg, 10 mg, 15 mg and 25 mg are packed in PVC/Aclar and aluminium blister foil.

Each blister pack contains 7 capsules. Each carton contains either a single blister pack (7's pack size) or three blister packs (21's pack size).

Not all pack sizes may be marketed.

Holder of Certificate of Registration

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LENALIDOMIDE CIPLA 15: 53/32/0375.372

LENALIDOMIDE CIPLA 25: 53/32/0376.373

Access to the corresponding professional information

The corresponding professional information of this medicine can be found in the packaging