PATIENT INFORMATION LEAFLET

POMALIDOMIDE CIPLA Capsules

SCHEDULING STATUS

S4

POMALIDOMIDE 1 mg CIPLA (hard capsules)

POMALIDOMIDE 2 mg CIPLA (hard capsules)

POMALIDOMIDE 3 mg CIPLA (hard capsules)

POMALIDOMIDE 4 mg CIPLA (hard capsules)

Pomalidomide

Contains sugar (isomalt 25,1 mg/ 1 mg capsules; 50,2 mg/ 2 mg capsules; 75,3 mg/ 3 mg capsules and 100,4 mg/ 4 mg capsules)

Read all of this leaflet carefully before you start taking POMALIDOMIDE 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.
- POMALIDOMIDE 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.

POMALIDOMIDE CIPLA is expected to cause severe birth defects and may lead to the death of an unborn baby.

• Do not take this medicine if you are pregnant or could become pregnant.

• You must follow the contraception advice described in this leaflet.

What is in this leaflet:

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

What POMALIDOMIDE CIPLA is

POMALIDOMIDE CIPLA contains the active substance, pomalidomide. This medicine is related to thalidomide and belongs to a group of medicines called immunosuppressants, which regulate how your immune system works.

What POMALIDOMIDE CIPLA is used for

POMALIDOMIDE CIPLA is used in combination with other medicine called dexamethasone, to treat adult patients who have become worse, with a type of cancer called ‘multiple

myeloma', despite having at least two other treatments - including lenalidomide and bortezomib.

What is multiple myeloma

Multiple myeloma is a type of blood cancer which affects a certain kind of white blood cell, called the plasma cell, which produces antibodies.

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

Do not take POMALIDOMIDE CIPLA if:

- you are pregnant or think you may be pregnant or are planning to become pregnant, as POMALIDOMIDE CIPLA **is harmful to an unborn child** (see **section 'Pregnancy, breastfeeding and fertility'**).
- you can become pregnant unless you follow all the necessary measures to prevent you from becoming pregnant. If you can become pregnant, your doctor will record with each prescription that the necessary measures have been taken and will provide you with this confirmation.
- you are allergic (hypersensitive) to pomalidomide or any of the other ingredients of POMALIDOMIDE CIPLA listed in the following **section: 'What POMALIDOMIDE CIPLA contains'**. If you think you may be allergic, ask your doctor for advice.
- you are a male patient unable to follow or comply with the required contraceptive measures.

If any of these apply to you, tell your doctor before you take POMALIDOMIDE CIPLA.

Warnings and precautions

Talk to your doctor, pharmacist or nurse before taking POMALIDOMIDE CIPLA if:

- you had blood clots in the past. During the treatment with POMALIDOMIDE CIPLA you have an increased risk of developing blood clots in the veins and arteries. Your doctor may recommend you take additional treatments (e.g. warfarin) or lower the dose of POMALIDOMIDE CIPLA to reduce the chance that you get blood clots.
- you have ever had an allergic reaction such as rash, itching, swelling, feeling dizzy or trouble breathing while taking related medicines called ‘thalidomide’ or ‘lenalidomide’.
- you have had a heart attack, have heart failure, have difficulty breathing, or if you smoke, have high blood pressure or high cholesterol levels.
- 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. You may also experience an uneven heartbeat. This condition is called tumour lysis syndrome.
- you have or have had neuropathy (nerve damage causing tingling or pain in your hands or feet).
- you have or have ever had hepatitis B infection. Treatment with POMALIDOMIDE CIPLA may cause the hepatitis B 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 experience or 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) or drug hypersensitivity syndrome, Toxic

Epidermal Necrolysis (TEN) or Stevens-Johnson Syndrome (SJS). See also **section 4 "Possible side effects"**.

It is important to note that patients with multiple myeloma treated with POMALIDOMIDE CIPLA may develop additional types of cancer, therefore your doctor should carefully evaluate the benefit and risk when you are prescribed this medicine.

At any time during or after your treatment, tell your doctor or nurse immediately if you have:

- blurred vission,
- 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 POMALIDOMIDE CIPLA, tell your doctor about any change in these symptoms.

Blood donation and blood tests

You should not donate blood during treatment and for 7 days after the end of treatment. Before and during the treatment with POMALIDOMIDE CIPLA you will have regular blood tests. This is because your medicine may cause a fall in the number of blood cells that help fight infection (white cells) and in the number of cells that help to stop bleeding (platelets).

Your doctor should ask you to have a blood test:

- before treatment
- every week for the first 8 weeks of treatment
- at least every month after that for as long as you are taking POMALIDOMIDE CIPLA.

As a result of these tests, your doctor may change your dose of POMALIDOMIDE CIPLA or stop your treatment. The doctor may also change the dose or stop the medicine because of your general health.

Children and adolescents

POMALIDOMIDE CIPLA is not recommended for use in children and adolescents under 18 years, as no data is available for this population.

Other medicines and POMALIDOMIDE 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:

- some antifungals such as ketaconazole,
- some antibiotics (for example ciprofloxacin, enoxacin),
- certain antidepressants such as fluvoxamine.

Taking POMALIDOMIDE CIPLA with food and drink

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

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, contraception and breastfeeding – information for women and men

Women

Do not take POMALIDOMIDE CIPLA if you are pregnant, think you may be pregnant or are planning to become pregnant. This is because this medicine is expected to harm the unborn baby. Before starting the treatment, you should tell your doctor if you are able to become pregnant, even if you think this is unlikely.

If you are able to become pregnant:

- you must use effective methods of contraception for at least 4 weeks before starting treatment, for the whole time you are taking treatment, and until at least 4 weeks after stopping treatment. Talk to your doctor about the best method of contraception for you.
- each time your doctor writes a prescription for you, he will ensure you understand the necessary measures that have to be taken to prevent pregnancy.
- your doctor will arrange pregnancy tests before treatment, at least every 4 weeks during treatment, and at least 4 weeks after the treatment has finished.

If you become pregnant despite the prevention measures:

- you must stop the treatment immediately and talk to your doctor straight away.

Breastfeeding

Do not take POMALIDOMIDE CIPLA if you are breastfeeding, or intend to breastfeed your baby.

Men

POMALIDOMIDE CIPLA passes into human semen.

- If your partner is pregnant or able to become pregnant, you must use condoms for the whole time you are taking treatment and for 4 weeks after the end of treatment.
- You should not donate semen or sperm during treatment and for 4 weeks after the end of treatment.

Driving and using machines

Do not drive or operate machines if you experience side effects, such as dizziness, tiredness, sleepiness or blurred vision.

It is not always possible to predict to what extent POMALIDOMIDE CIPLA may interfere with the daily activities of patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which POMALIDOMIDE CIPLA affects them.

POMALIDOMIDE CIPLA contains sugar (isomalt)

POMALIDOMIDE CIPLA contains sugar in the form of isomalt, which may have a mild laxative effect. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

3. How to take POMALIDOMIDE CIPLA

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

Always take your POMALIDOMIDE CIPLA exactly as described in his leaflet or as your doctor, or pharmacist or nurse has told you. Check with your doctor, pharmacist or nurse if you are not sure.

POMALIDOMIDE CIPLA is taken alone or in combination with dexamethasone.

Your doctor will prescribe the correct dose for your condition.

Your doctor may need to reduce the dose of POMALIDOMIDE CIPLA, dexamethasone or stop one or more of these medicines based on the results of your blood tests, your general condition, other medicines you may be taking (e.g. ciprofloxacin, enoxacin and fluvoxamine) and if you experience side effects (especially rash or swelling) from treatment.

- Do not break, open or chew the capsules. If powder from a broken POMALIDOMIDE CIPLA capsule makes contact with the skin, wash the skin immediately and thoroughly with soap and water.
- Swallow the capsules whole, preferably with water.
- You can take the capsules either with or without food.
- Take POMALIDOMIDE CIPLA at about the same time each day.

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

Duration of the treatment with POMALIDOMIDE CIPLA

POMALIDOMIDE CIPLA, dexamethasone are taken in 'treatment cycles'. Each cycle lasts 21 days (3 weeks). You should continue the cycles of treatment until your doctor tells you to stop.

If you take more POMALIDOMIDE 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 POMALIDOMIDE CIPLA

If you forget to take POMALIDOMIDE CIPLA on a day when you should, take your next capsule as normal the next day. Do not take a double dose to make up for forgotten individual doses.

4. Possible side effects

POMALIDOMIDE CIPLA can have side effects.

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

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

- Swelling of face, lips, tongue and throat, which may cause difficulty breathing (due to serious types of allergic reaction called angioedema and anaphylactic reaction).
- Widespread rash, high body temperature, enlarged lymph nodes and other body organ involvement (Drug Reaction with Eosinophilia and Systemic Symptoms which is also

known as DRESS or drug hypersensitivity syndrome, Toxic Epidermal Necrolysis or Stevens-Johnson Syndrome). Stop using pomalidomide if you develop these symptoms and contact your doctor or seek medical attention immediately. See also **section 2.**

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

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

- Fever, chills, sore throat, cough, mouth ulcers or any other signs of infection (due to less white blood cells, which fight infection).
- Bleeding or bruising without a cause, including nosebleeds and bleeding from the bowels or stomach (due to effects on blood cells called 'platelets').
- Rapid breathing, rapid pulse, fever and chills, passing very little to no urine, nausea and vomiting, confusion, unconsciousness (due to infection of blood called sepsis or septic shock).
- Severe, persistent or bloody diarrhoea (possibly with stomach pain or fever) caused by a bacterial infection called *Clostridium difficile*.
- Chest pain, or leg pain and swelling, especially in your lower leg or calves (caused by blood clots).
- Shortness of breath (from serious chest infection, inflammation of the lung, heart failure or a blood clot).

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

Tell your doctor if you notice any of the following:

Frequent side effects:

- Infections of the lungs (pneumonia and bronchitis).
- Infections of the nose, sinuses and throat, caused by bacteria or viruses.
- Low red blood cells, which may cause anaemia leading to tiredness and weakness.
- High blood levels of potassium (hyperkalaemia), which may cause abnormal heart rhythm.
- Low blood levels of potassium (hypokalaemia), which may cause weakness, muscle cramps, muscle aches, palpitations, tingling or numbness, dyspnoea, mood changes.
- High blood levels of sugar (hyperglycaemia), which may cause increased thirst and a dry mouth, needing to pee frequently, tiredness, blurred vision, unexplained weight loss.
- Low blood level of phosphate (hypophosphatemia), which may cause muscle weakness and irritability or confusion.
- Low blood levels of magnesium (hypomagnesaemia), which may cause tiredness, generalised weakness, muscle cramps, irritability and may result in low blood levels of calcium (hypocalcaemia), which may cause numbness and, or tingling of hands, feet, or lips, muscle cramps, muscle weakness, light-headedness, confusion.
- Low blood levels of sodium (hyponatraemia), which may cause tiredness and confusion, muscle twitching, fits (epileptic seizures) or coma.
- High blood levels of uric acid (hyperuricaemia), which may cause a form of arthritis called gout.
- High blood level of calcium (hypercalcaemia), which may cause slowing reflexes and skeletal muscle weaknesses.
- Loss of appetite.

- Constipation, diarrhoea or nausea.
- Being sick (vomiting).
- Lack of energy.
- Difficulty in falling asleep or staying asleep (insomnia).
- Dizziness, tremor.
- Muscle spasm, muscle weakness.
- Bone pain, back pain.
- Numbness, tingling or burning sensation to the skin, pains in hands or feet (peripheral sensory neuropathy).
- Swelling of the body, including swelling of the arms or legs (deep vein thrombosis).
- Depression.
- A spinning feeling in your head, making it difficult to stand up and move normally (vertigo).
- Blurred or clouding of vision (cataract).
- A fast and irregular heartbeat (atrial fibrillation).
- Damage to the kidney.
- Inability to pass urine.
- Abnormal liver test.
- Urinary tract infection, which may cause a burning sensation when passing urine, or a need to pass urine more often.
- Pain in the pelvis.
- Heart attack (chest pain spreading to the arms, neck, jaw, feeling sweaty and breathless, feeling sick or vomiting).
- Chest pain, chest infection.
- Increased blood pressure.

- Low blood pressure, which may cause dizziness or fainting.
- Flu-like symptoms (influenza).
- Sore or dry mouth.
- Changes in the way things taste.
- Abdominal pain, swollen abdomen.
- Feeling confused.
- Fall.

Less frequent side effects:

- Certain types of skin cancer (squamous cell carcinoma and basal cell carcinoma), which can cause changes in the appearance of your skin or growths on your skin. If you notice any changes to your skin whilst taking POMALIDOMIDE CIPLA, tell your doctor as soon as possible.
- Recurrence of hepatitis B infection, which can cause yellowing of the skin and eyes, dark brown-coloured urine, right-sided abdominal pain, fever and feeling nauseous or being sick.

Tell your doctor straightaway if you notice any of these symptoms:

- Bone pain.
- Bleeding within the skull.
- Decreased ability to move or feel (sensation) in your hands, arms, feet and legs because of nerve damage (peripheral sensorimotor neuropathy).
- Numbness, itching, and a feeling of pins and needles on your skin (paraesthesia).
- Swelling caused by fluid.
- Hives (urticaria).

- Rashes.
- Itchy skin.
- Shingles.
- A fall in the number of red and white blood cells and platelets at the same time (pancytopenia), which will make you more prone to bleeding and bruising. You may feel tired and weak, and short of breath and you are also more likely to get infections.
- Decreased number of lymphocytes (one type of white blood cells) often caused by infection (lymphopenia).
- High blood levels of uric acid, which may cause a form of arthritis called gout.
- Low blood pressure, which may cause dizziness or fainting.
- Abdominal pain, swollen abdomen.
- Inability to pass urine.
- Stroke.
- Inflammation of the liver (hepatitis) which can cause itchy skin, yellowing of the skin and the whites of the eyes (jaundice), pale coloured stools, dark coloured urine and abdominal pain.
- The breakdown of cancer cells resulting in the release of toxic compounds into the bloodstream (tumour lysis syndrome). This can result in kidney problems.
- Underactive thyroid gland, which may cause symptoms such as tiredness, lethargy, muscle weakness, slow heart rate, weight gain.
- If you feel fatigue, sudden weight gain, constipation, dry skin, puffy face, hoarseness, muscle weakness, aches, tenderness, and stiffness, joint pain, or swelling, irregular menstrual periods or amenorrhea, dry hair or hair loss (hypothyroidism).
- Dizziness.
- Tremor.

- Loss of appetite.

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 or telephone: 0802226662. By reporting side effects, you can help provide more information on the safety of POMALIDOMIDE CIPLA.

5. How to store POMALIDOMIDE CIPLA

Store all medicines out of reach of children.

Store at or below 30 °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 POMALIDOMIDE CIPLA contains

The active substance is: Pomalidomide

The other ingredients are:

Isomalt (E 953)

Pregelatinized starch

Sodium stearyl fumarate

Composition of empty **1 mg** capsule shell:

Gelatin

Titanium dioxide (E171)

Yellow iron oxide (E172)

Composition of empty **2 mg** capsule shell:

Gelatin

Titanium dioxide (E171)

Yellow iron oxide (E172)

Red iron oxide (E172)

Composition of empty **3 mg** capsule shell:

Gelatin

Titanium dioxide (E171)

Brilliant blue FCF-FD&C Blue 1 (E133)

Composition of empty **4 mg** capsule shell:

Gelatin

Titanium dioxide (E171)

FD&C Red #3 (E127)

Brilliant blue FCF-FD&C Blue 1 (E133)

Composition of printing ink are:

Shellac

Dehydrated alcohol

Isopropyl alcohol

Butyl alcohol

Propylene glycol

Purified water

Strong ammonia solution

Potassium hydroxide

Black iron oxide (E172)

What POMALIDOMIDE CIPLA looks like and contents of the pack

POMALIDOMIDE 1 mg CIPLA capsule has a yellow opaque cap and yellow opaque body, capsule shell size No. 4 imprinted in black ink with “LP” on the cap and “664” on the body and containing yellow granular powder.

POMALIDOMIDE 2 mg CIPLA capsule has an orange opaque cap and orange opaque body, capsule shell size No. 3 imprinted in black ink with “LP” on the cap and “665” on the body and containing yellow granular powder.

POMALIDOMIDE 3 mg CIPLA capsule has a light green opaque cap and light green opaque body, capsule shell size No. 2 imprinted in black ink with “LP” on the cap and “690” on the body and containing yellow granular powder.

POMALIDOMIDE 4 mg CIPLA capsule has a blue opaque cap and blue opaque body, capsule shell size No. 2 imprinted in black ink with “LP” on the cap and “667” on the body and containing yellow granular powder.

POMALIDOMIDE CIPLA is packed in transparent PVC/Aclar-aluminum blisters and aluminum-aluminum blisters.

Each pack contain 21 capsules

Holder of Certificate of Registration

CIPLA MEDPRO (PTY) LTD.

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Customer Care: 080 222 6662

This leaflet was last revised in

Registration number

POMALIDOMIDE 1 mg CIPLA: 56/32/0540

POMALIDOMIDE 2 mg CIPLA: 56/32/0541

POMALIDOMIDE 3 mg CIPLA: 56/32/0542

POMALIDOMIDE 4 mg CIPLA: 56/32/0543

Access to the corresponding Professional Information

To access corresponding Professional Information, scan the QR Code below.

PLACE HOLDER: The QR Code to be generated and included after approval.