PATIENT INFORMATION LEAFLET

SCHEDULING STATUS S4

POMARZA 1

POMARZA 2

POMARZA 3

POMARZA 4

Pomalidomide

1 mg / 2 mg / 3 mg / 4 mg

Hard gelatin capsule

Contains sugar (lactose):

POMARZA 1: each hard gelatin capsule contains 25 mg anhydrous lactose.

POMARZA 2: each hard gelatin capsule contains 50 mg of anhydrous lactose.

POMARZA 3: each hard gelatin capsule contains 75 mg of anhydrous lactose.

POMARZA 4: each hard gelatin capsule contains 100 mg of anhydrous lactose.

Read all of this leaflet carefully before you start taking POMARZA

- 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.
- POMARZA 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.

What is in this leaflet:

WARNING: SEVERE LIFE-THREATENING HUMAN BIRTH DEFECTS

Pomalidomide is structurally related to thalidomide. Thalidomide is a known human teratogenic active substance that causes severe life-threatening birth defects.

If Pomalidomide is taken during pregnancy, it will cause severe birth defects and may lead to death of an unborn baby.

You must follow the contraception advice described in this leaflet.

BECAUSE OF THIS TOXICITY AND IN AN EFFORT TO MAKE THE CHANCE OF FOETAL EXPOSURE TO POMARZA AS NEGLIGIBLE AS POSSIBLE, POMARZA IS APPROVED FOR MARKETING UNDER A SPECIAL RESTRICTED DISTRIBUTION PROGRAMME.

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

WARNING: BLOOD CLOTS IN VEINS AND ARTERIES

(VENOUS THROMBO EMBOLISM)

Deep Venous Thrombosis (blood clots in the veins and arteries) and Pulmonary Embolism (blood clots in the lungs) occur in patients with multiple myeloma treated with POMARZA. Your doctor may prescribe other medicines to prevent this from happening after assessing your risk factors (see "Take special care with POMARZA").

1. What POMARZA is and what it is used for

POMARZA contains a medicine called pomalidomide.

POMARZA belongs to a group of medicines called immunomodulatory medicines, which is a group of medicines which affects the body's immune system (the body's natural defences).

POMARZA is used to treat adult patients with a type of cancer called multiple myeloma.

Multiple myeloma affects a certain type of white blood cell (called the 'plasma cell'). These cells grow out of control and then accumulate in the bone marrow, which results in damage to the bones and kidneys.

POMARZA is used either with:

- two other medicines - called 'bortezomib' (a type of chemotherapy medicine) and 'dexamethasone' (an anti-inflammatory medicine) in people who have received at least one other previous treatment - including lenalidomide.
- one other medicine - called 'dexamethasone' in people whose myeloma has become worse, despite having received at least two other treatments - including lenalidomide and bortezomib.

2. What you need to know before you take POMARZA

Your doctor will manage you according to the requirements of the RISK MANAGEMENT PROGRAMME to ensure that you take POMARZA in a safe manner.

Do not take POMARZA if:

- you are allergic (hypersensitive) to pomalidomide or to any of the other ingredients of POMARZA listed in section 6.
- you are pregnant or think you may be pregnant or are planning to become pregnant, as POMARZA is expected to be harmful to an unborn child (see 'Take special care with POMARZA' and 'Pregnancy, breastfeeding and fertility').
- you are able to become pregnant and you are not using or are not able to use effective contraceptive measures to prevent pregnancy (see 'Take special care with POMARZA' and 'Pregnancy, breastfeeding and fertility') and as outlined in the RISK MANAGEMENT PROGRAMME.
- you are a male patient and you are not able to follow or comply with the required contraceptive measures (see 'Take special care with POMARZA' and 'Pregnancy, breastfeeding and fertility').

If you are uncertain whether any of the conditions above apply to you, talk to your doctor, pharmacist or nurse before taking POMARZA.

Warnings and precautions

Take special care with POMARZA in the following situations:

For women taking POMARZA

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

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).
- 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.

If you become pregnant despite the prevention measures

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

For men taking POMARZA

POMARZA passes into human semen.

If your female partner is pregnant or able to become pregnant, 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 POMARZA should not donate sperm or semen during treatment including dose interruptions and for 4 weeks following the end of treatment.

All patients

- if you have ever had blood clots in the past, during the treatment with POMARZA you have an increased risk of getting blood clots in your veins and arteries. Your doctor may recommend that you take additional treatments (e.g. warfarin) or lower the dose of POMARZA to reduce the chance of you getting blood clots.
- if 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 may have an increased risk of an allergic reaction to POMARZA. Talk to your doctor, pharmacist or nurse before taking POMARZA.
- 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. You may also experience an uneven heartbeat. This condition is called tumour lysis syndrome.
- if you see signs of bleeding, including nose bleeds.
- if you suffer from thyroid conditions (underactive thyroid).
- if you suffer from heart conditions, or have had previous problems with your heart.
- if you experience any problems with your lung, e.g., difficulty in breathing.
- your doctor will monitor your liver function while you are taking POMARZA.
- there may be an increased risk of infections while you are using POMARZA. Please notify your doctor if you feel ill or have a fever.

- You may feel dizzy or experience fatigue or confusion while you are using POMARZA.
- If you experience new or worsening neurological, cognitive or behavioural signs or symptoms, your doctor may need to evaluate you for Progressive multifocal leukoencephalopathy (PML).

It is important to take into consideration that patients with multiple myeloma being treated with POMARZA may develop additional types of cancer, therefore your doctor should carefully evaluate the benefit and risk when you are prescribed POMARZA.

Blood donation and blood tests

You should not donate blood during treatment and for 4 weeks after the end of treatment. Before and during the treatment with POMARZA you will have regular blood tests. This is because POMARZA 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 POMARZA

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

At the end of the treatment, you should return all unused capsules to the pharmacist.

Children and adolescents

POMARZA is not to be taken by children below the age of 18 years.

Other medicines and POMARZA

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

(This includes complementary or traditional medicines).

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

- some medicines used to treat fungal infections such as ketoconazole.
- certain antidepressants such as fluvoxamine.

- warfarin.

POMARZA with food and drink and alcohol

Capsules can be taken either with or without food (see 'How to take POMARZA').

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 health care provider for advice before taking this medicine.

Pregnancy

Women and men taking POMARZA must not become pregnant or father a child. This is because POMARZA is expected to harm the unborn baby. You and your partner should use effective methods of contraception while taking POMARZA.

For women taking POMARZA, you must not take POMARZA if you are pregnant, as it is expected to be harmful for an unborn baby. In addition, you must not become pregnant while taking POMARZA. 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 two effective methods of contraception for 4 weeks before starting treatment, for the whole time you are taking treatment, and until 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 or she will ensure you understand the necessary measures that have to be taken to prevent pregnancy.
- your doctor will arrange pregnancy tests before treatment, every 4 weeks during treatment, and 4 weeks after the treatment has finished.

If you do become pregnant during treatment with POMARZA, you must stop taking the capsules and inform your doctor immediately.

For men taking POMARZA, please see 'Take special care with POMARZA'. POMARZA 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.
- If your partner becomes pregnant whilst you are taking POMARZA, you should inform your doctor immediately and it is recommended that your partner seek medical advice.

Breastfeeding

You must not breastfeed you baby while taking POMARZA.

Driving and using machines

POMARZA may cause possible side effects such as confusion, dizziness, tiredness or sleepiness and affect mental and/or physical abilities to perform or execute tasks or activities requiring mental alertness, judgment and/or sound coordination and vision e.g., driving, riding, flying, sailing, operating machines/ equipment (see 'Possible side effects'). If this happens to you, do not drive or operate tools or machinery.

POMARZA contains lactose

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 POMARZA

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

Always take POMARZA exactly as your doctor or pharmacist has told you.

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

Your doctor will tell you how long your treatment with POMARZA will last. Do not stop your treatment plan early.

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

POMARZA must be given to you by a doctor with experience in treating multiple myeloma.

POMARZA is taken in combination with another medicine called dexamethasone or bortezomib. See the leaflet that comes with the other medicines for further information on its use and effects.

POMARZA and the other medicines are taken in treatment cycles, with each cycle lasting 28 days (4 weeks).

Your doctor will decide on the dosage which is appropriate for you, based on your disease, your body mass and the other medicines that you take with it.

No dosage adjustment is required for older patients taking POMARZA. Your doctor will decide if the dosage of the other products will need to be adjusted.

After completing each cycle, you will be required to start a new one.

Your doctor may need to reduce the dose of POMARZA or dexamethasone or stop the treatment based on the results of your blood tests, your general condition and if you experience any side effects from your treatment.

If you suffer from liver or kidney problems your doctor will check your condition very carefully whilst you are receiving POMARZA.

How to take POMARZA

- do not break, open or chew the capsules. If powder from a broken capsule makes contact with the skin, wash the skin immediately and thoroughly with soap and water.
- healthcare professionals, caregivers and family members should wear disposable gloves when handling the capsule. Gloves should then be removed carefully to prevent skin exposure, placed in a sealable plastic polyethylene bag and disposed of in accordance with local requirements. Hands should then be washed thoroughly with soap and water. Women who are pregnant or suspect they may be pregnant should not handle the capsule.
- swallow the capsules whole, preferably with water.
- you can take the capsules either with or without food.
- capsules should be taken at about the same time each day.

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

If you take more POMARZA 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 POMARZA

If you forget to take POMARZA on a day when you should, take your next capsule as normal the next day. Do not increase the number of capsules you take to make up for not taking POMARZA the previous day.

If you stop taking POMARZA

Unless your doctor instructs you to stop treatment, it is important to continue taking POMARZA.

If you stop treatment and your original symptoms come back tell your doctor or pharmacist immediately.

4. Possible side effects

POMARZA can have side effects.

Not all side effects reported for POMARZA are included in this leaflet.

Should your general health worsen or if you experience any untoward effects while taking POMARZA, please consult your doctor, pharmacist or other health care professional for advice.

If any of the following happens, stop taking POMARZA and tell your doctor, pharmacist or healthcare provider immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing.
- rash or itching.

These are all very serious side effects. This may be due to an allergic (hypersensitivity) reaction. 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, sore throat, cough, or any other signs of infection (due to reduced number of white blood cells, which fight infection).
- bleeding or bruising without a cause (due to effects on blood cells called 'platelets').

- 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 or 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 in the lungs.
- a fall in the number of red blood cells which may cause anaemia leading to tiredness and weakness.
- loss of appetite.
- shortness of breath (dyspnoea).
- constipation, diarrhoea or nausea.
- muscle spasm, bone pain.
- swelling of the body, including swelling of the arms or legs.
- infections of the nose, sinuses and throat.
- an infection of the blood caused by bacteria.
- high blood levels of potassium, which can cause abnormal heart rhythm.
- low blood levels of sodium, which can cause tiredness and confusion, muscle twitching, fits (epileptic seizures) or coma.
- feeling confused.
- loss of consciousness.
- numbness, tingling or burning sensation to the skin, pains in hands or feet, dizziness, tremor.
- a spinning feeling in your head, making it difficult to stand up and move normally.
- vomiting.
- rashes.
- itchy skin.
- kidney failure.

- inability to pass urine.
- pain in the pelvis.
- abnormal liver test.

Less frequent side effects

- yellowing of the skin and the whites of the eyes (jaundice).
- a fall in the number of red and white blood cells and platelets at the same time (pancytopenia). You will be more prone to bleeding and bruising. You may feel tired and weak, and short of breath. You are also more likely to get infections.
- the breakdown of cancer cells resulting in the release of toxic compounds into the bloodstream (tumour lysis syndrome). This can result in kidney problems.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell 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 POMARZA.

5. How to store POMARZA

Store at or below 25 °C.

Keep the capsules in the original container until required for use.

Do not store in bathrooms.

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

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

Keep all medicines out of the reach and sight of children.

6. Contents of the pack and other information

What POMARZA contains

The active substance is pomalidomide.

POMARZA 1: each hard gelatin capsule contains 1,0 mg of pomalidomide.

POMARZA 2: each hard gelatin capsule contains 2,0 mg of pomalidomide.

POMARZA 3: each hard gelatin capsule contains 3,0 mg of pomalidomide.

POMARZA 4: each hard gelatin capsule contains 4,0 mg of pomalidomide.

Contains sugar (lactose):

POMARZA 1: each hard gelatin capsule contains 25 mg anhydrous lactose.

POMARZA 2: each hard gelatin capsule contains 50 mg of anhydrous lactose.

POMARZA 3: each hard gelatin capsule contains 75 mg of anhydrous lactose.

POMARZA 4: each hard gelatin capsule contains 100 mg of anhydrous lactose.

The other ingredients are anhydrous Lactose NF, pregelatinized starch NF and sodium stearyl fumarate NF.

What POMARZA looks like and contents of the pack

Hard gelatin capsule.

POMARZA 1: Light yellow to yellow coloured powder filled into hard gelatin capsule shells with purple coloured cap and dark pink coloured body imprinted  and 1 mg on cap & '520' on body with white ink.

POMARZA 2: Light yellow to yellow coloured powder filled into hard gelatin capsule shells with purple coloured cap and pink opaque coloured body imprinted  and 2 mg on cap & '519' on body with white ink.

POMARZA 3: Light yellow to yellow coloured powder filled into hard gelatin capsule shells with purple coloured cap and violet opaque coloured body imprinted  and 3 mg on cap & '518' on body with white ink.

POMARZA 4: Light yellow to yellow coloured powder filled into hard gelatin capsule shells with purple coloured cap and purple opaque coloured body imprinted  and 4 mg on cap & '517' on body with white ink.

POMARZA 1 / 2 / 3 / 4 – pack size of 21's: HDPE container 75 cc with a CR Plastic cap with Pulp Liners, 33

mm

POMARZA 1 – pack size of 100's: HDPE container 75 cc with a CR Plastic cap with Pulp Liners, 33 mm

POMARZA 2 / 3 / 4 – pack size of 100's: HDPE container 100 cc with a CR Plastic cap with Pulp Liners, 38 mm

POMARZA 1 / 2 / 3 / 4 – pack size of 10's and 21's: Aluminium foil paper backed peel push, plain and cold formable foil

Not all strengths and pack sizes may be marketed.

Holder of Certificate of Registration

Dr. Reddy's Laboratories (Pty) Ltd.

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2191

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Registration number

POMARZA 1: 59/32/0092

POMARZA 2: 59/32/0093

POMARZA 3: 59/32/0094

POMARZA 4: 59/32/0095

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 web site:

http://www.drreddys.co.za