PATIENT INFORMATION LEAFLET FOR POMYLO

SCHEDULING STATUS

S4

POMYLO 1 mg, 2 mg, 3 mg and 4 mg hard capsules

Pomalidomide

Contains sugar (mannitol)

Read all of this leaflet carefully before you start taking POMYLO

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- POMYLO 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:

Pomalidomide is structurally related to thalidomide. Thalidomide is a known active substance that causes severe life-threatening birth defects in humans. Pomalidomide was found to have similar life-threatening birth defects on both rats and rabbits (see **Do not take POMYLO.** If POMYLO is taken during pregnancy, life-threatening birth defects in humans are expected. **BECAUSE OF THIS TOXIC EFFECT AND IN AN EFFORT TO MAKE THE CHANCE OF EXPOSURE DURING PREGNANCY TO POMYLO AS NEGLIGIBLE AS POSSIBLE, POMYLO IS APPROVED FOR USE UNDER A SPECIAL RESTRICTED DISTRIBUTION PROGRAMME. THIS PROGRAMME IS CALLED THE ACTIVE RISK MANAGEMENT PROGRAM. UNDER THIS RESTRICTED DISTRIBUTION PROGRAMME, ONLY DOCTORS REGISTERED WITH THE PROGRAMME ARE ALLOWED TO PRESCRIBE THE PRODUCT AND PHARMACISTS REGISTERED WITH THE PROGRAMME ARE**

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ALLOWED TO DISPENSE THE PRODUCT. IN ADDITION, YOU MUST BE ADVISED OF, AGREE TO, AND COMPLY WITH THE REQUIREMENTS OF THE ACTIVE RISK MANAGEMENT PROGRAM.

WARNING: BLOOD CLOTS IN THE VEINS AND ARTERIES (VENOUS THROMBEMBOLISM):
Deep vein thrombosis (blood clots in the veins and arteries) and pulmonary embolism (blood clots in the lungs) occur in patients with multiple myeloma treated with POMYLO. Your doctor may tell you to take other medicines to prevent this from happening after assessing your risk factors (see Take special care with POMYLO.

What is in this leaflet

1. What POMYLO is and what it is used for

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

POMYLO is used with another medicine called 'dexamethasone' (an anti-inflammatory medicine) to treat adults with a type of cancer called 'multiple myeloma'. It is used in people whose myeloma has become worse, despite having received at least two other kinds of treatment.

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2. What you need to know before you take POMYLO

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

Do not take POMYLO:

- If you are allergic (hypersensitive) to pomalidomide or any of the other ingredients of POMYLO (see section 6). If you think you may be allergic, ask your doctor for advice.
- If you are pregnant or think you may be pregnant or planning to become pregnant, as POMYLO is harmful to an unborn child (see sections: **Take special care with POMYLO** and **Pregnancy and breastfeeding**).
- If you are able to become pregnant, unless you follow all the necessary measures to prevent you from becoming pregnant (see sections: **Take special care with POMYLO** and **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 will provide you with this confirmation.
- If you are a male patient and you are not able to follow or comply with the required contraceptive measures (see sections: **Take special care with POMYLO** and **Pregnancy and breastfeeding**)

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

Warnings and precautions

Tell your doctor or healthcare provider before taking POMYLO:

- If you had blood clots in the past. During treatment with POMYLO you have an increased risk of developing blood clots in the veins and arteries.
- If you have had a heart attack, other heart problems, have ever had a blood clot, or if you smoke, have high blood pressure or high cholesterol levels. Your doctor will regularly monitor your symptoms.

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- Before treatment with POMYLO, your doctor may test your thyroid function because POMYLO could cause your thyroid to be underactive.
- If you have weakness, numbness and pain from nerve damage, usually in the hands and feet (peripheral neuropathy).
- If you have previously experienced 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 (see **Possible side effects**).
- If you have had an allergic reaction whilst taking thalidomide or pomalidomide (other medicine used to treat Multiple Myeloma) such as rash, itching, swelling, dizziness or trouble breathing.
- If you have kidney problems. Your doctor may adjust your dose of POMYLO based on this information.
- If you have any signs of an infection, such as a cough or fever.
- If you have or have ever had previous viral infection, particularly: hepatitis B infection, varicella zoster, HBV. If you are unsure, talk to your doctor. Treatment with POMYLO 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.

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

Take special care with POMYLO:

For women taking POMYLO:

Before starting the 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) except in the case of confirmed tubal sterilisation.
- You must use two effective methods of contraception for 4 weeks before starting the 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 POMYLO:

POMYLO 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 at least 4 weeks after the end of treatment (even if you have undergone a vasectomy).

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

All patients:

Before and during treatment with POMYLO you will have regular blood tests as POMYLO may cause a fall 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:

- Before treatment.
- Every week for the first 8 weeks of treatment.
- At least every month after that.

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Your doctor may adjust your dose of POMYLO or stop your treatment based on the results of your blood tests and on your general condition.

Your doctor may check if you have a high total amount of tumours throughout your 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').

It is important to note that patients with multiple myeloma treated with POMYLO may develop additional types of cancer, therefore your doctor may check you for changes to your skin such as red spots or rashes.

You may also be evaluated by your doctor for any signs or symptoms of heart or lung problems before and during treatment with POMYLO.

Interstitial lung disease (ILD), scarring of lung tissue, have been reported with the use of POMYLO. Your doctor will carefully asses you for worsening of lung symptoms to exclude ILD.

Your doctor will regularly monitor your liver function for the first 6 months of treatment with POMYLO, and as needed thereafter.

At any time during or after your treatment, tell your doctor or nurse immediately if you:
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 POMYLO, tell your doctor about any change in these symptoms.

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

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

Women who are pregnant or suspect they may be pregnant should not handle the blister or capsule.

Children and adolescents:

POMYLO is not recommended for children and adolescents under 18 years because of insufficient evidence.

Other medicines and POMYLO

Always tell your healthcare provider if you are taking any other medicine. (This includes all 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
- certain antibiotics used to treat bacterial infections such as ciprofloxacin

POMYLO with food and drink

This medicine should be swallowed, preferably with water, with or without food (see section 3).

Pregnancy and breastfeeding

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If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking this medicine.

Pregnancy:

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

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

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

For men taking POMYLO:

If your partner becomes pregnant whilst you are taking POMYLO, you should inform your doctor immediately. It is recommended that your partner seeks medical advice. You must use effective methods of contraception.

Breastfeeding:

You should not breastfeed when taking POMYLO.

Contraception:

For women taking POMYLO*:*

Before starting the treatment, 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 every treatment, at least every 4 weeks during treatment, and at least 4 weeks after the

treatment has finished).

AND

- You must use effective methods of contraception for at least 4 weeks before starting treatment, during treatment, and until at least 4 weeks after stopping treatment. Your doctor will advise you on appropriate methods of contraception.

For men taking POMYLO:

POMYLO 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 for at least 4 weeks after the end of treatment, even if you have had a vasectomy.

Driving and using machines

POMYLO may cause possible side effects such as confusion, dizziness, tiredness or sleepiness and may affect mental and/or physical abilities to perform or execute tasks or activities requiring mental alertness, judgment and/or sound coordination and vision. Do not drive or operate machines if you experience side effects.

POMYLO contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per capsule, therefore it is considered essentially ‘sodium-free’.

3. How to take POMYLO

Do not share medicines prescribed for you with any other person.
POMYLO must be given to you by a doctor with experience in treating multiple myeloma. POMYLO is taken in combination with another medicine called dexamethasone.
Always take POMYLO exactly as your doctor has told you. Check with your doctor if you are unsure.

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Your doctor will prescribe the correct dose for your condition.

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

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

You should take POMYLO at about the same time each day.

POMYLO and dexamethasone are taken in treatment cycles.

- Each cycle lasts 28 days (4 weeks).

How much to take:

The usual starting dose is 4 mg POMYLO taken once a day.

In every 4-week cycle, POMYLO should be taken once a day for 3 weeks, followed by a week off. This means:

- Days 1 to 21: take POMYLO once a day.
- Days 22 to 28: do not take POMYLO.

Dexamethasone:

The usual starting dose of dexamethasone is 40 mg per day. In every 4-week cycle a dose of dexamethasone should be taken on the first day of each week only. This means:

- Days 1, 8, 15 and 22 of each cycle: take a dose of dexamethasone.
- Days 2 to 7, 9 to 14, 16 to.21 and·23 to 28: do not take dexamethasone.

Older patients:

For patients above the age of 75 years the usual starting dose of dexamethasone is

reduced to 20 mg per day. After completing each cycle, start a new one.

Your doctor may need to reduce the dose of POMYLO or dexamethasone or stop the treatment based on the results of your blood tests, your general condition and if you experience side effects from treatment. If you suffer from liver or kidney problems your doctor will check your condition very carefully whilst you are receiving POMYLO.

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

Duration of the treatment with POMYLO

You should continue the cycles of treatment until your doctor tells you to stop.

If you take more POMYLO than you should

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

If you forget to take a dose of POMYLO

If you forget to take POMYLO 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 POMYLO the previous day.

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

4. Possible side effects

POMYLO can cause side effects.

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

Should your general health worsen, or if you experience any untoward effects while taking POMYLO, please consult your healthcare provider for advice.

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

- Swelling of your hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing.
- Rash or itching.
- Fainting.

These are all very serious side effects. If you have them, you may have had a serious reaction to POMYLO. 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), dangerously low blood pressure due to sever infection (septic shock).
- 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.
- 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 POMYLO, tell your doctor as soon as possible.
- Treatment with POMYLO can cause a decrease in the numbers of red and white blood cells and platelets in your blood.
  You may experience a reduction in the number of:
  - Platelets, which may make you more prone to bruising, or to bleeding without obvious injury (e.g. bleeding from your bowels, stomach, mouth and gums or bleeding in the brain or bleeding in the liver)

  - Red blood cells, which can cause anaemia, with symptoms such as tiredness, weakness and paleness
  - White blood cells, which may make you more prone to getting flu-like symptoms and infections or severe infection (sepsis). Symptoms may include fever, chills, sore throat, cough, mouth ulcers, shortness of breath.
- The breakdown of cancer cells resulting in the release of toxic compounds into the bloodstream (tumour lysis syndrome). This can result in kidney problems
- Bleeding within the skull (intracranial haemorrhage), stroke (damage to the brain from interruption of its blood supply)
- 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), heart disorders (e.g. changes in the way your heart beats, chest pain or discomfort, fast or slow irregular heartbeat, obstruction in blood flow to your heart), shortness of breath especially when lying down (which may be a symptom of heart failure)
- 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 or blood clot)
- Bleeding in the intestines
- Inflammation of the liver (hepatitis) which may cause yellow skin or eyes (jaundice), nausea, abdominal pain, fatigue and fever
- An allergic reaction which may begin as a rash in one area but spread with extensive loss of skin over the whole body, including Stevens-Johnson syndrome (SJS), toxic epidermal necrolysis (TEN) and leukocytoclastic vasculitis
- Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS) syndrome, a severe allergic reaction (symptoms include skin rash, fever, and inflammation of the liver, lung, and heart)

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- Reduced amount of urine, swelling of your legs, ankles, and feet from retention of fluids caused by the failure of the kidneys to eliminate water waste, condition where your kidneys suddenly stop working properly .

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, including bacterial, viral or fungal, sinus infection (pressure behind the eyes and the cheeks, runny, stuffy nose), sore throat, sneezing, coughing, tiredness, body aches, inflammation of the colon caused by the bacteria *Clostridium difficile*, flu, urinary tract infection.
- Wheezing, shortness of breath or a dry cough, which may be symptoms caused by inflammation of the tissue in the lungs, may occur.
- Infection of the lungs, upper and lower respiratory tract.
- Fever and flu like symptoms including fever, muscle ache, headache, and chills.
- Decreased appetite, high or low levels of potassium and low levels of urea in your blood, low levels of sodium in your blood which can cause tiredness and confusion, muscle twitching, fits (epileptic seizures), high blood sugar, low levels of magnesium or phosphate in your blood, high or low levels of calcium in your blood.
- Feeling confused, inability to sleep (insomnia), depression
- Loss of consciousness, weakness, numbness and pain from nerve damage, usually in the hands and feet (peripheral neuropathy), dizziness, tremor, burning or prickling sensation that is usually felt in the hands, arms, legs, or feet, altered taste, fainting
- Spinning sensation (vertigo)
- Clouding of the eye (cataract)
- High or low blood pressure

- Shortness of breath (dyspnoea), nosebleeds
- Diarrhoea, nausea (feeling sick), constipation, vomiting (being sick), abdominal pain, painful swelling and sores inside the mouth, dry mouth, bloating and swelling in the belly area
- Rash, itching, dry skin
- Bone pain, muscle spasms, muscle weakness, back pain
- Urinary retention
- Pelvic pain
- Tiredness, fever, swelling of your lower legs or hands, chest pain
- Decrease neutrophil, white blood cell and platelet count, increased liver enzymes.
- Fall.

Less frequent side effects:

- Increase in blood pressure within blood vessels that supply the lungs (pulmonary hypertension)
- Abnormal increase of bilirubin in your blood which may indicate liver damage and may result in jaundice.

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 or pharmacist.

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. By reporting side effects, you can help provide more information on the safety of POMYLO.

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5. How to store POMYLO

Store at or below 30 °C.

Do not remove capsule from blister until required for use.

Store all medicines out of reach of children.

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

Return all unused medicine to your pharmacist.

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

6. Contents of the pack and other information

What POMYLO contains:

The active substance is pomalidomide.

Each POMYLO 1 hard capsule contains 1 mg pomalidomide.

Each POMYLO 2 mg hard capsule contains 2 mg pomalidomide.

Each POMYLO 3 mg hard capsule contains 3 mg pomalidomide.

Each POMYLO 4 mg hard capsule contains 4 mg pomalidomide.

The other ingredients are croscarmellose sodium, mannitol, pregelatinized starch, sodium stearyl fumarate.

The capsule shell of POMYLO 1 mg and 3 mg contains gelatine, FD&C Blue 2 (E132), iron oxide yellow (E172) and titanium dioxide (E171).

The capsule shell of POMYLO 2 mg contains gelatine, FD&C Blue 2 (E132), FD&C Red 3 (E127), iron oxide yellow (E172) and titanium dioxide (E171).

The capsule shell of POMYLO 4 mg contains gelatine, FD&C Blue 2 (E132) and titanium dioxide (E171).

What POMYLO looks like and contents of the pack

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POMYLO 1 mg: Dark blue cap and yellow body size “4” capsules printed with “NAT” with white ink on cap and “1 mg” with black ink on body of the capsule, contains light yellow to yellow coloured powder.

POMYLO 2 mg: Dark blue cap and orange body size “2” capsules printed with “NAT” with white ink on cap and “2 mg” with white ink on body of the capsule, contains light yellow to yellow coloured powder.

POMYLO 3 mg: Dark blue cap and green body size “2” capsules printed with “NAT” with white ink on cap and “3 mg” with white ink on body of the capsule, contains light yellow to yellow coloured powder.

POMYLO 4 mg: Dark blue cap and blue body size “2” capsules printed with “NAT” with white ink on cap and “4 mg” with white ink on body of the capsule, contains light yellow to yellow coloured powder.

White HDPE bottle with child resistant cap.
Clear transparent PVC/Aclar film with plain aluminium foil blisters containing 7 hard capsules per blister strip. The blisters are packed into cartons.
Pack size: 21 capsules.

Holder of the certificate of registration

Forrester Pharma (Pty) Ltd
2 Waterford Mews
Waterford Place
7441
Century City
Cape Town
South Africa

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POMYLO 2 mg: 56/32.2/0190

POMYLO 3 mg: 56/32.2/0191

POMYLO 4 mg: 56/32.2/0192