1.3.2 Patient Information Leaflet

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS:

S4

IMNOVID® 1 mg (hard capsules)

IMNOVID® 2 mg (hard capsules)

IMNOVID® 3 mg (hard capsules)

IMNOVID® 4 mg (hard capsules)

Pomalidomide, 1 mg; 2 mg; 3 mg; 4 mg

Contains sugar: Mannitol

Read all of this leaflet carefully before you start taking IMNOVID

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- IMNOVID 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 in both rats and rabbits (see ‘Do not take

IMNOVID" Pregnancy and breastfeeding and fertility'). If Pomalidomide is taken during pregnancy, life-threatening birth defects in humans are expected.

BECAUSE OF THIS TOXICITY AND IN AN EFFORT TO MAKE THE CHANCE OF FOETAL EXPOSURE TO IMNOVID AS NEGLIGIBLE AS POSSIBLE, IMNOVID IS APPROVED FOR MARKETING UNDER A SPECIAL RESTRICTED DISTRIBUTION PROGRAMME. THIS PROGRAMME IS CALLED THE KEY ASSIST RISK MANAGMENT 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, YOU MUST BE ADVISED OF, AGREE TO, AND COMPLY WITH THE REQUIREMENTS OF THE KEY ASSIST RISK MANAGEMENT PROGRAMME.

WARNING: BLOOD CLOTS IN THE 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 IMNOVID. Your doctor may prescribe other mediicnes to prevent this from happening after assessing your risk factors (see "Take special care with IMNOVID").

What is in this leaflet

1. What IMNOVID is and what it is used for.
2. What you need to know before you take IMNOVID**.**
3. How to take IMNOVID**.**
4. Possible side effects.

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5. How to store IMNOVID**.**

6. Contents of the pack and other information.

1. What IMNOVID is and what it is used for

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

IMNOVID is also used in combination with two other medicines called 'bortezomib' and 'dexamethasone' to treat adult patients with a type of cancer called 'multiple myeloma'. It is used in people who have received at least one previous treatment including a product called 'lenalidomide'.

IMNOVID 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.

2. What you need to know before you take IMNOVID

Your doctor will have enrolled you in the KEY ASSIST RISK MANAGEMENT PROGRAMME to ensure that IMNOVID is used safely.

Do not take IMNOVID:

- If you are pregnant or think you may be pregnant or are planning to become pregnant, **as IMNOVID is expected to be harmful to an unborn child** (see sections: 'Take special care with IMNOVID' and 'Pregnancy and breastfeeding and fertility').
- If you are able to become pregnant and you are not using or are not able to use effective contraceptive measures to prevent pregnancy (see sections: 'Take special care

with IMNOVID' and 'Pregnancy and breastfeeding and fertility') and as outlined in the **KEY ASSIST RISK MANAGEMENT PROGRAMME**.

- If you are allergic (hypersensitive) to pomalidomide or any of the other ingredients of IMNOVID listed in the following section: 'What IMNOVID contains'. If you think you may be allergic, ask your doctor for advice.
- 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 IMNOVID' and 'Pregnancy and 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 IMNOVID.

Warnings and precautions

Take special care with IMNOVID:

Please talk to your doctor in the following situations:

For women taking IMNOVID

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)
- 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 IMNOVID

IMNOVID 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 IMNOVID 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 IMNOVID you have an increased risk of getting blood clots in your veins and arteries. Your doctor may recommend you take additional treatments (e.g. warfarin) or lower the dose of IMNOVID to reduce the chance that you get 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 IMNOVID. Talk to your doctor, pharmacist or nurse before taking IMNOVID.
- 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.

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- If you suffer from thyroid conditions (underactive thyroid).
- If you suffer froma 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 using IMNOVID.
- There may be an increased risk of infections while you are using IMNOVID. Please notify your doctor if you feel ill or have a fever.

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

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 IMNOVID 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 IMNOVID.

As a result of these tests, your doctor may change your dose of IMNOVID 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.

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Children/ and adolescents

Do not give IMNOVID to children younger than 18 years because of insufficient evidence.

Other medicines and IMNOVID:

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 ketaconazole;
- certain antidepressants such as fluvoxamine.

IMNOVID with food and drink and alcohol

The IMNOVID capsules can be taken either with or without food (see following Section: 'How and when to take IMNOVID').

Pregnancy and breastfeeding and fertility:

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before taking IMNOVID

Pregnancy:

The following must be followed as stated in the Key Assist Programme. Women and men taking IMNOVID must not become pregnant or father a child. This is because IMNOVID (pomalidomide) is expected to harm the unborn baby. You and your partner should use effective methods of contraception while taking IMNOVID.

For women taking IMNOVID, you must not take IMNOVID if you are pregnant, as it is expected to be harmful for an unborn baby. In addition, you must not become pregnant while taking IMNOVID. 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 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 the treatment with IMNOVID, you must stop the treatment and inform your doctor immediately.

For men taking IMNOVID, please see section: ‘Take special care with IMNOVID’. IMNOVID 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 IMNOVID, you should inform your doctor immediately. It is recommended that your partner seeks medical advice.

Breastfeeding:

You must not breastfeed you baby while taking IMNOVID.

Driving and using machinery:

IMNOVID may cause possible side-effects such as 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')

IMNOVID contains mannitol

IMNOVID contains mannitol which may have an effect on the control of your blood sugar if you have diabetes mellitus.

IMNOVID contains mannitol and may have a laxative effect.

If you have been told that you have an intolerance to some sugars, you should not take IMNOVID.

3. How to take IMNOVID:

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

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

IMNOVID 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.

Always take your medicines exactly as your doctor has told you. Check with your doctor, pharmacist or nurse if you are not sure.

IMNOVID and the other medicines are taken in treatment cycles.

- Each cycle lasts 28 days (4 weeks).

How much to take:

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

Older patients

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

After completing each cycle, start a new one.

Your doctor may need to reduce the dose of IMNOVID 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 IMNOVID.

Children and adolescents

IMNOVID is not usually used in children and young people under 18 years. Your doctor will decide if it is appropriate to use IMNOVID in younger patients.

All patients

How and when to take IMNOVID

- Do not break, open or chew the capsules. If powder from a broken IMNOVID 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 IMNOVID at about the same time each day.

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

Duration of the treatment with IMNOVID

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

If you take more IMNOVID 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 center.

If you forget to take IMNOVID

If you forget to take IMNOVID 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 IMNOVID the previous day.

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

4. Possible side effects

IMNOVID can cause side effects.

Not all side effects reported for IMNOVID are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking this medicine, please consult your doctor, pharmacist or other healthcare professional for advice.

If any of the following happens, stop taking IMNOVID and tell your doctor 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. If you have them, you may have had a serious allergic reaction to IMNOVID. 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:

More frequently occurring side effects:

- Infections of 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 frequently occurring 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 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 or nurse. This includes any possible side effects not listed in this leaflet. 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 IMNOVID.

5. How to store IMNOVID

Store at or below 25 °C.

Store in the original container until required for administration.

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).

Store all medicines out of the reach of children.

6. Contents of the pack and other information

What IMNOVID contains:

The active substance is pomalidomide.

Each IMNOVID 1 mg hard capsule contains 1,0 mg of pomalidomide

Each IMNOVID 2 mg hard capsule contains 2,0 mg of pomalidomide

Each IMNOVID 3 mg hard capsule contains 3,0 mg of pomalidomide

Each IMNOVID 4 mg hard capsule contains 4,0 mg of pomalidomide

Contains sugar: Mannitol

The other ingredients are:

Mannitol, pregelatinised starch, sodium stearyl fumarate and a gelatin capsule shell.

Capsule shell:

1 mg capsule shell contains gelatin, titanium dioxide (E171), indigotine (E132) and yellow iron oxide (E172) and white and black ink.

2 mg capsule shell contains gelatin, titanium dioxide (E171), indigotine (E132), yellow iron oxide (E172), erythrosin (E127) and white ink.

3 mg capsule shell contains gelatin, titanium dioxide (E171), indigotine (E132), yellow iron oxide (E172), and white ink.

4 mg capsule shell contains gelatin, titanium dioxide (E171), indigotine (E132), brilliant blue FCF (E133) and white ink.

Printing ink:

1 mg capsule shell contains: white ink - shellac, titanium dioxide (E171), simethicone, propylene glycol (E1520) and ammonium hydroxide (E527). Black ink - shellac, iron oxide black (E172), propylene glycol (E1520) and ammonium hydroxide (E527).

2 mg capsule shell contains: white ink – shellac, titanium dioxide (E171), simethicone, propylene glycol (E1520) and ammonium hydroxide (E527).

3 mg capsule shell contains: white ink – shellac, titanium dioxide (E171), simethicone, propylene glycol (E1520) and ammonium hydroxide (E527).
4 mg capsule shell contains: white ink – shellac, titanium dioxide (E171), simethicone, propylene glycol (E1520) and ammonium hydroxide (E527)

What IMNOVID looks like and contents of the pack

Clear colourless polyvinylchloride (PVC) / Polychlorotrifluoroethylene (PCTFE) / Aluminium foil blisters. The blisters are packed in a cardboard carton. Each pack contains 21 capsules.
IMNOVID 1 mg: Dark blue opaque cap on yellow opaque body, imprinted with black ink on body and white ink on cap, size 3, hard gelatin capsules.
IMNOVID 2 mg: Dark blue opaque cap on orange opaque body, imprinted with white ink on cap and body, size 1, hard gelatin capsules.
IMNOVID 3 mg: Dark blue opaque cap on green opaque body, imprinted with white ink on cap and body, size 1, hard gelatin capsules.
IMNOVID 4 mg: Dark blue opaque cap on blue opaque body, imprinted with white ink on cap and body, size 1, hard gelatin capsules.

Holder of Certificate of Registration and Manufacturer

Key Oncologics (Pty) Ltd
39 Eleventh Avenue
Houghton Estate, 2198
Johannesburg
Tel: +27 (11) 480 0060

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Registration numbers

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Imnovid 2 mg - 49/32.2/0745

Imnovid 3 mg - 49/32.2/0746

Imnovid 4 mg - 49/32.2/0747

Access to the corresponding Professional Information

Can be obtained on the SAHPRA website https://www.sahpra.org.za

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