1.3.2.1 Patient Information Leaflet

PATIENT INFORMATION LEFALET

SCHEDULING STATUS

S4

THALIDOMIDE 50 mg BMS (hard capsules)

Thalidomide

Sugar free

Read all of this leaflet carefully before you start taking THALIDOMIDE 50 mg BMS

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.
- THALIDOMIDE 50 mg BMS 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

1.3.2.1 Patient Information Leaflet

1. What THALIDOMIDE 50 mg BMS is and what it is used for

THALIDOMIDE 50 mg BMS belongs to a group of medicines known as immunosuppressive agents. This is a type of medicine that acts on the cells involved in the body's immune system.

THALIDOMIDE 50 mg BMS is used in combination with two other medicines, melphalan and prednisone, for the treatment of patients with untreated multiple myeloma aged 65 years or more, or those patients who cannot receive high dose chemotherapy.

THALIDOMIDE 50 mg BMS in combination with dexamethasone is used for the treatment of patients with untreated multiple myeloma.

THALIDOMIDE 50 mg BMS on its own is used for the treatment of relapsing or refractory multiple myeloma.

THALIDOMIDE 50 mg BMS is also used for the acute treatment of the skin symptoms associated with moderate to severe erythema nodosum leprosum (ENL) which can occur if you have leprosy.

If you have any questions about how THALIDOMIDE 50 mg BMS works or why this medicine has been prescribed for you, please ask your doctor.

2. What you need to know before you take THALIDOMIDE 50 mg BMS

You will have been given specific instructions by your doctor, particularly on the effects of THALIDOMIDE 50 mg BMS on unborn babies (outlined in the THALIDOMIDE RISK MANAGEMENT PROGRAMME (TRMP).

You will have been given an educational brochure for patient by your doctor. Read it carefully and follow the related instructions.

If you do not fully understand these instructions, please ask your doctor to explain them again before you take THALIDOMIDE 50 mg BMS. See also further information in this section under “Warnings and precautions” and “Pregnancy and breastfeeding”.

Do not take THALIDOMIDE 50 mg BMS / should not be administered to you:

- if you are hypersensitive (allergic) to thalidomide or any of the other ingredients of THALIDOMIDE 50 mg BMS (listed in section 6);
- if you are pregnant, think you may be pregnant or are planning to become pregnant or you are breastfeeding;
- if you are not using or are not able to use reliable contraceptive measures to prevent pregnancy as outlined in the THALIDOMIDE RISK MANAGEMENT PROGRAMME (TRMP);
- if you are unable to follow or comply with the instructions set out in the THALIDOMIDE RISK MANAGEMENT PROGRAMME (TRMP).

Warnings and precautions

Follow your doctor’s instructions carefully. You will have been given specific instructions by your doctor particularly on the effects of THALIDOMIDE 50 mg BMS on unborn babies. If

you have not fully understood these instructions, please ask your doctor again before taking THALIDOMIDE 50 mg BMS.

Your doctor will have enrolled you in the THALIDOMIDE RISK MANAGEMENT PROGRAMME (TRMP) to ensure that THALIDOMIDE 50 mg BMS is used safely.

For all patients

Take special care with THALIDOMIDE 50 mg BMS:

- you do not understand the contraception advice given to you by your doctor or if you do not feel able to follow this advice.
- you have had a heart attack, have ever had a blood clot in the past, or if you smoke, have high blood pressure or high cholesterol levels. During the treatment with THALIDOMIDE 50 mg BMS you have an increased risk of developing blood clots in the veins and arteries (see also section 4 “Possible side effects”).
- you have experienced or have existing neuropathy i.e. nerve damage causing tingling, abnormal co-ordination or pain in your hands or feet (see also section 4 “Possible side effects”).
- you experienced or have existing slow heart rate (this may be a symptom of bradycardia).
- you have high blood pressure in the arteries of the lungs (see also section 4 “Possible side effects”).
- you have a fall in the number of white blood cells (neutropenia) accompanied by fever and infection.
- you have a fall in the number of platelets. You will be more prone to bleeding and bruising.
- you have or have had injury to the liver (hepatic disorders) including abnormal liver test

results.

- you experience or have experienced in the past severe skin reactions called Stevens-Johnson syndrome, toxic epidermal necrolysis or drug reaction with eosinophilia and systemic symptoms (which is also known as DRESS or drug hypersensitivity syndrome). (For description of symptoms see section 4 “Possible side effects”).
- you have had an allergic reaction whilst taking THALIDOMIDE 50 mg BMS such as rash, itching, swelling, dizziness or trouble breathing.
- you have experienced sleepiness.
- you have experienced fever, chills and severe shaking, and possibly complicated by low blood pressure and confusion (these may be symptoms of severe infections).
- you have or have ever had previous viral infection, particularly varicella zoster, hepatitis B infection, or HIV. If you are in doubt, talk to your doctor. Treatment with THALIDOMIDE 50 mg BMS may cause a virus to become active again in patients who carry it, resulting in a recurrence of the infection. Your doctor should check whether you have ever had hepatitis B infection.
- you have kidney or liver problems (see also section 4 “Possible side effects”).

Your thyroid function may be checked before you take THALIDOMIDE 50 mg BMS and monitored during treatment.

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 THALIDOMIDE 50 mg BMS, tell your doctor about any change in these symptoms.

Your doctor may check 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 body which can lead to kidneys failure (this condition is called Tumour Lysis Syndrome) (see also section 4 “Possible side effects”).

Your doctor should evaluate if you develop additional types of haematological malignancies (called acute myeloid leukaemia and myelodysplastic syndromes) during your treatment with THALIDOMIDE 50 mg BMS (see also section 4 “Possible side effects”).

You must not donate blood during THALIDOMIDE 50 mg BMS treatment and for at least 7 days after stopping treatment.

Children/ and adolescents

Do not give THALIDOMIDE 50 mg BMS to children below the age of 12 years.

Other medicines and THALIDOMIDE 50 mg BMS

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:

- cause sleepiness as thalidomide may increase their effects. This includes sedatives

(such as anxiolytics, hypnotics, antipsychotics, H1 antihistamines, opiate derivatives and barbiturates).

THALIDOMIDE 50 mg BMS may increase the effects of:

- medicines called benzodiazepines which can be used to help you sleep and reduce anxiety,
- medicines that slow the heart rate (induce bradycardia, such as anticholinesterases and beta blockers),
- medicines that are used for heart problems and complications (such as digoxin), or for thinning the blood (such as warfarin),
- are associated with neuropathy such as other treatments for cancer,
- are used for contraception,
- antihypertensives medicines which are used to treat high blood pressure,
- muscle relaxants such as baclofen which may also make you feel sleepy.

Make sure you tell your doctor if you are taking medicines for any of these conditions, as THALIDOMIDE 50 mg BMS may increase the effects of these medicines.

THALIDOMIDE 50 mg BMS may interact with some medicines such as:

- zalcitabine,
- stavudine,
- didanosine,
- vincristine,
- doxorubicin.

THALIDOMIDE 50 mg BMS with food and drink and alcohol

THALIDOMIDE 50 mg BMS can enhance the drowsiness caused by alcohol; therefore, you should not drink alcohol while you are taking THALIDOMIDE 50 mg BMS.

Pregnancy and breastfeeding and fertility

Pregnancy:

You should not take THALIDOMIDE 50 mg BMS if you are pregnant or breastfeeding your baby.

If you are pregnant, think you may be pregnant or are planning to become pregnant you should not take THALIDOMIDE 50 mg BMS. Thalidomide is known to cause damage to unborn babies and can result in severe birth defects or death of the baby. Just one capsule taken by a pregnant woman can cause a baby to have serious birth defects such as missing or severely deformed arms and legs. They may have problems with their eyes or ears, cleft palates, and problems with their internal organs.

Women who can become pregnant should not use THALIDOMIDE 50 mg BMS unless adequate contraceptive methods as outlined in the THALIDOMIDE RISK MANAGEMENT PROGRAMME (TRMP) are used to prevent pregnancy. You need to begin using TWO methods of birth control at least 4 weeks before you start taking THALIDOMIDE 50 mg BMS and continue using birth control methods for the duration of your therapy and for one month following cessation of your treatment. Prior to being prescribed THALIDOMIDE 50 mg BMS your doctor may perform a pregnancy test and may perform further tests at monthly intervals throughout your treatment.

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Before starting to take THALIDOMIDE 50 mg BMS and throughout treatment, you must use one highly effective method of contraception such as birth control pills (‘the pill’), implantable hormone capsules, injectable contraception, intrauterine device (IUD), or suitable surgical methods as determined by your doctor throughout the duration of your THALIDOMIDE 50 mg BMS therapy and for one month following the end of your treatment. You must also use one additional effective method such as condoms, the cervical cap, or the diaphragm AT THE SAME TIME.

Male patients with female partners of childbearing potential should use adequate contraceptive methods as outlined in the THALIDOMIDE RISK MANAGEMENT PROGRAMME (TRMP). Thalidomide can be found in a male patient's semen. Male patients should use a condom with every sexual intercourse with a female partner. If you are a male patient with an allergy to condoms, any female sexual partner must use at least one very effective method of birth control, such as birth control pills, implantable hormone capsules, injectable contraception, intrauterine device or IUD, or suitable surgical methods as determined by your doctor. Your partner should start such birth control methods at least one month prior to the start of a sexual relationship and continue throughout your THALIDOMIDE 50 mg BMS treatment and for one additional month following cessation of THALIDOMIDE 50 mg BMS.

If you have sexual BMS without birth control even once, you must stop taking THALIDOMIDE 50 mg BMS and tell your doctor.

Should contraception fail, any resulting pregnancy may incur damage to the baby and consequently if you are a female capable of conceiving a child and you miss a period during

treatment you must stop treatment and inform your doctor immediately. If you are male patient and your female partner is capable of conceiving a child and she misses a period during your treatment you must inform your doctor immediately.

Breastfeeding

You should not take THALIDOMIDE 50 mg BMS if you are breastfeeding or begin breastfeeding until eight weeks after stopping treatment.

Driving and using machinery

THALIDOMIDE 50 mg BMS is known to cause drowsiness and sleepiness. If affected, you should not drive or not operate any tools or machines.

It is not always possible to predict to what extent THALIDOMIDE 50 mg BMS may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which THALIDOMIDE 50 mg BMS affects them.

THALIDOMIDE 50 mg BMS is sugar free.

3. How to take THALIDOMIDE 50 mg BMS

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

Always take THALIDOMIDE 50 mg BMS exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The usual dose is:

200 to 400 mg (for multiple myeloma) or 100 to 400 mg (for erythema nodosum leprosum) per day, taken orally with a glass of water.

To reduce the effect of drowsiness during the day, THALIDOMIDE 50 mg BMS can be taken in the evening at least one hour after food. THALIDOMIDE 50 mg BMS may also be divided into two separate daily doses, one in the morning and one in the evening if preferred. Both doses should be taken at least one hour after food.

Thalidomide Celgene is not suitable for patients under the age of 12.

Depending on how THALIDOMIDE 50 mg BMS affects you, your doctor may choose to alter the dose.

Your doctor will tell you how long your treatment with THALIDOMIDE 50 mg BMS will last.

If you have the impression that the effect of THALIDOMIDE 50 mg BMS is too strong or too weak, tell your doctor or pharmacist.

- Take this medicine by mouth.
- Swallow the capsules whole with a full glass of water.
- Do not crush or chew.
- Take the capsules as a single dose before going to bed. This will make you less likely to feel sleepy at other times.

If you take more THALIDOMIDE 50 mg BMS than you should

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

If you forget to take THALIDOMIDE 50 mg BMS

Do not take a double dose to make up for forgotten individual doses.

4. Possible side effects

THALIDOMIDE 50 mg BMS can have side effects.

Not all side effects reported for THALIDOMIDE 50 mg BMS are included in this leaflet.

Should your general health worsen or if you experience any untoward effects while taking THALIDOMIDE 50 mg BMS, please consult your healthcare provider for advice.

If any of the following happens, stop taking THALIDOMIDE 50 mg BMS 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;
- fainting.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to THALIDOMIDE 50 mg BMS. 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:

- Pain in your hands and feet, numbness, tingling or abnormal co-ordination:

  This is due to nerve damage. It may become very severe, painful and disabling. If you experience such symptoms, speak to your doctor immediately, who may reduce the dose or discontinue the treatment. This side effect usually happens after you have been taking THALIDOMIDE 50 mg BMS for several months but can happen sooner than this. It can also happen sometime after treatment has stopped. It may not go away or may go away slowly.
- Sudden pain in your chest or difficulty in breathing.

  This may be due to blood clots in the artery leading to your lungs. These can happen during treatment, or after treatment has stopped.
- Pain or swelling in your legs, especially in your lower leg or calves.

  This may be due to blood clots in the veins of your leg. These can happen during treatment, or after treatment has stopped.

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

Tell your doctor if you notice any of the following:

- Constipation, indigestion, feeling sick (nausea), being sick (vomiting), dry mouth, inflammation of the cells lining your stomach wall, a hole in part of your large bowel (colon) which can cause infection, bowel obstruction.
- Rash, dryness of the skin, very serious skin reactions (toxic epidermal necrolysis and Stevens Johnson Syndrome).

- Numbness and tingling, feeling dizzy, sleepiness, feeling tired, shaking (tremor), headache, having short term difficulty seeing or speaking, difficulty in co-ordinating movement, seizure.
- Swelling of hands and feet, fever, feeling generally unwell, feeling weak, faint or unsteady, lack of energy or strength.
- Depression, confusion, mood changes, anxiety.
- Slow heart rate, heart failure.
- Low blood cell counts. This may mean that you are more likely to develop infections. Your doctor may monitor your blood cell counts during treatment with THALIDOMIDE 50 mg BMS.
- Low blood pressure, a spinning feeling in your head, making it difficult to stand up and move normally.
- Chest infection (pneumonia), inflammation and swelling of the tubes in your lungs (bronchitis).
- Shortness of breath, difficulty breathing, lung disease.
- Muscle cramps.
- Blurred vision.
- Sexual dysfunction.
- Underactive thyroid (hypothyroidism).

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

f you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via 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 THALIDOMIDE 50 mg BMS.

5. How to store THALIDOMIDE 50 MG BMS

Store all medicines out of reach of children.

Store below 25 °C, protected from light.

Keep the blister in the carton until required for use.

Do not store in a bathroom

Do not use after the expiry date stated on the label / carton / bottle

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 THALIDOMIDE 50 mg BMS contains:

The active substance is thalidomide.

The other ingredients are:

Magnesium stearate, pregelatinised starch, a hard capsule shell (gelatin, Titanium dioxide) and printing in (shellac, black iron oxide, propylene glycol).

What THALIDOMIDE 50 mg BMS looks like and contents of the pack:

White opaque size 0 capsules, marked in black: ‘THALIDOMIDE BMS 50 mg’.

14 capsules are packed in an Aclar/aluminium foil laminate blister. 28 capsules are packed in a cardboard wallet.

Holder of Certificate of Registration and Manufacturer

Key Oncologics (Pty) Ltd

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South Africa

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Access to the corresponding Professional Information

Can be obtained on the SAHPRA website