

**Patient package insert in accordance with the pharmacists' regulations (preparations) - 1986**

This medicine is dispensed only by a physician's prescription

## **Thalidomide BMS<sup>®</sup> 50 mg hard capsules**

**Name and quantity of the active ingredient:**

**Each capsule contains:** Thalidomide 50 mg

Inactive ingredients - See section "Additional information".

**Read this package insert carefully in its entirety before using this medicine and every time this medicine is prescribed to you, as it may contain newer information. It is recommended to read this insert with another family member.**

This leaflet contains summary information about this medicine. If you have any further questions, refer to the physician or the pharmacist.

This medicine has been prescribed for treating your illness. Do not pass it on to others. It may harm them, even if it seems to you that their medical condition is similar to yours.

**Do not give this medicine to a child under the age of 12 years.**

**Safety and efficacy in children younger than 12 years have not been established.**

**Thalidomide has caused severe birth defects when taken during pregnancy. Thalidomide should never be used by women who are pregnant or who could become pregnant whilst taking the medicine or could become pregnant within 4 weeks after stopping the medicine. Even a single dose can cause birth defects.**

### **1. What is this medicine intended for?**

This medicine is indicated for the treatment of multiple myeloma and certain symptoms of leprosy.

**Therapeutic group:** Immunosuppressive agent

## 2. Before using this medicine

### **Do not use this medicine if:**

#### Women:

**! Do not use this medicine if you are pregnant, think you may be pregnant or are planning to become pregnant or are breastfeeding.** When taken during pregnancy, Thalidomide BMS 50 mg hard capsules causes birth defects (infants with disabilities) and death to a foetus, and may affect your developing foetus.

Thalidomide BMS 50 mg hard capsules should never be used by women who are pregnant, and women of childbearing potential who are not using, not willing or not able to use adequate contraceptive measures to prevent pregnancy, or not willing to choose continuous abstinence from heterosexual sexual activity as a contraceptive method in order to prevent pregnancy (please see **Special warnings regarding the use of the medicine**).

You must wait 4 weeks after the end of the treatment before trying to get pregnant.

**! Breastfeeding - do not use Thalidomide BMS 50 mg hard capsules if you are breastfeeding. Do not begin breastfeeding within 4 weeks after stopping the treatment.**

#### Men:

**! Do not use this medicine if you are not able or willing to comply with adequate contraceptive measures** (please see **Special warnings regarding the use of the medicine**).

**Male patients who are taking Thalidomide BMS 50 mg hard capsules should use a condom during every sexual encounter with a female partner of childbearing potential, during treatment, during dose interruptions and for 4 weeks after stopping treatment, even if you have undergone a successful vasectomy.**

**! Do not donate semen while taking the medicine, during any breaks (interruptions) in your treatment, and for 4 weeks after stopping the medicine.**

#### All patients:

**! Do not donate blood during treatment and for 4 weeks after stopping treatment.**

**! Do not take Thalidomide BMS 50 mg hard capsules if you are aware of a hypersensitivity (allergic) to thalidomide, or any of the other ingredients of Thalidomide BMS 50 mg hard capsules - see section 6: "Additional information".**

### **Special warnings regarding the use of the medicine:**

**Do not use this medicine without consulting a physician before starting treatment.**

#### **Women taking Thalidomide BMS 50 mg hard capsules:**

Before starting the treatment, ask your physician whether you are of childbearing potential, even if you think it is unlikely, for example if you have stopped getting your period.

**Please note: The absence of menstruation as a result of cancer treatment does not rule out the risk of pregnancy.**

- Women of childbearing potential (including women who have chosen abstinence as a method of contraception), must undergo a pregnancy test in order to rule out pregnancy:
  - Before starting the treatment (around the time of receiving the prescription, but no later than 3 days before giving the prescription for Thalidomide BMS 50 mg hard capsules)
  - Every month during treatment – including during breaks between doses of Thalidomide BMS 50 mg hard capsules
  - 4 weeks after finishing treatment with Thalidomide
  
- Women of childbearing potential must use two types of contraception simultaneously each time (at least one very effective form, and one additional barrier form).
  - Starting at least 4 weeks before treatment with Thalidomide BMS 50 mg hard capsules
  - During the treatment
  - During treatment breaks and up to 4 weeks after stopping the treatment, unless abstinence from heterosexual sexual activity is your chosen contraception.

Your physician will instruct you on which contraception to use.

Effective methods of contraception include:

- Intrauterine device (IUD)
- Levonorgestrel-releasing intrauterine system (IUS)
- Medroxyprogesterone acetate injections
- Tubal ligation
- Sexual intercourse with a vasectomised male partner only; vasectomy must be confirmed by two negative semen analyses
- Ovulation inhibitory progesterone-only pills (i.e. desogestrel)

Combined oral contraceptive pills are not recommended because of the increased risk of blood clot formation and vascular occlusion in patients with multiple myeloma treated with this medicine.

Examples of barrier contraception are condoms, cervical cap, and diaphragm.

**Men taking Thalidomide BMS 50 mg hard capsules:**

Men taking Thalidomide BMS 50 mg hard capsules must always use a condom during sexual contact with a woman of childbearing potential, during the treatment, and for 4 weeks after stopping the treatment, even if they have had a vasectomy. If the man is sensitive (allergic) to latex or to polyurethane, he must abstain from having sexual intercourse with a woman of childbearing potential during the treatment with Thalidomide BMS 50 mg hard capsules, and for an additional 4 weeks after stopping the treatment.

If your partner falls pregnant while taking this medicine, inform the doctor immediately.

Men taking Thalidomide BMS 50 mg hard capsules cannot donate semen during the treatment – including during breaks in between doses of Thalidomide BMS 50 mg hard capsules – and up to 4 weeks after stopping the treatment.

**For all patients:**

Consult the physician if you have or have had any of the following medical conditions:

- Heart attack, blood clots, high blood pressure or high cholesterol
- Diabetes
- Frequent infections
- Hepatitis B virus infection
- Numbness, tingling or pain in your hands and feet
- Severe skin rash
- Seizures
- Thyroid problems
- You have had surgery in the previous 7 days or have wounds which are healing
- Kidney or liver problems.

If you have not told the physician about any of these conditions, tell him/her before you start taking Thalidomide BMS 50 mg hard capsules.

It is important to note that a small number of patients with multiple myeloma may develop additional types of cancer (regardless of their type of therapy). At this stage it cannot be ruled out that this risk may be slightly increased with Thalidomide BMS 50 mg hard capsules treatment. Therefore, your physician will carefully evaluate the benefit and risk when you are prescribed this medicine.

Dizziness - If you feel light-headed, dizzy or faint when getting out of bed or standing up, get up slowly. Standing up slowly, especially when you get up from bed or chairs, will help your body get used to the change in position and blood pressure. If this problem continues or gets worse, talk to your physician.

**Risk Management Program -**

Your physician will enrol you in the Risk Management Program/Pregnancy Prevention Program (RMP/PPP).

This program intends to help your physician advise you concerning the risks involved in thalidomide treatment and ensures that you are aware of the precautions that you should take before, during and after treatment.

Follow your physician's instructions carefully.

You should be given specific instructions by your physician particularly on the effects of thalidomide on fetuses.

If you have not fully understood these instructions, please ask your physician again before taking Thalidomide BMS 50 mg hard capsules.

**Men and women taking Thalidomide BMS 50 mg hard capsules cannot donate blood during the treatment and for 4 weeks after stopping the treatment.**

**Children and adolescents**

Do not give this medicine to a child under the age of 12 years.

Safety and efficacy in children younger than 12 years have not been established.

## **Drug interactions**

**Tell the physician or the pharmacist if you are taking or have recently taken other medicines, including non-prescription medicines, nutritional supplements or herbal medicines in order to prevent any risks or ineffectiveness resulting from drug interactions.**

It is especially important to inform your physician or pharmacist if you are taking:

- medicines that cause drowsiness, such as sleeping pills
- medicines used to treat depression or anxiety
- medicines used to treat heart problems and/or high blood pressure
- Hormonal contraceptives
- medicines used to treat anaemia
- hormone replacement therapy
- medicines used in the treatment of cancer such as vincristine
- medicines used in the treatment of AIDS such as zalcitabine and didanosine.

These medicines may be affected by Thalidomide BMS 50 mg hard capsules or may affect how the medicine works. You may need to take different amounts of your medicines, or you may need to take different medicines.

## **Taking this medicine with food**

This medicine should be taken with water, at least one hour after food.

## **Use of this medicine and alcohol consumption**

Do not drink wine or other alcoholic beverages during treatment with this medicine, since alcohol may increase the sedative effect of the medicine.

## **Pregnancy and Breastfeeding**

### **Pregnancy:**

Thalidomide causes severe birth defects or death of the foetus when taken during pregnancy.

- As little as one capsule taken by a pregnant woman can cause a baby to have serious birth defects.
- If you are pregnant, you must not take Thalidomide BMS 50 mg hard capsules. In addition, you must not become pregnant while taking Thalidomide BMS 50 mg hard capsules.

If you are of childbearing potential, you must use two methods of contraception simultaneously each time you have sexual intercourse (see section 2 "Before using this medicine").

You must stop the treatment and inform the physician immediately if:

- You miss or think you have missed a period, if you have irregular bleeding, or if you suspect you are pregnant.
- You have heterosexual intercourse without using reliable contraception.
- If you get pregnant during treatment with Thalidomide BMS 50 mg hard capsules, you must stop the treatment and inform the physician immediately.

Men who are taking Thalidomide BMS 50 mg hard capsules and have a partner of childbearing potential, please refer to section 2 "Before using this medicine".

If your partner gets pregnant during the treatment, you must inform the physician.

**Breastfeeding:**

Do not take Thalidomide BMS if you are breastfeeding. It is not known if thalidomide is passed into breast milk. However, as thalidomide is known to cause birth defects, do not breastfeed while you are receiving this medicine and for 4 weeks after the end of treatment.

**Driving and using machines:**

Do not drive or operate machinery until you know how Thalidomide BMS 50 mg hard capsules affect you.

This medicine may cause drowsiness or dizziness in some people.

**3. How should I use this medicine?**

Always use according to the physician's instructions. Your physician will choose the dose for you, monitor your progress and may adjust your dose. Your physician will tell you how many Thalidomide BMS hard capsules to take and for how long you will need to take them.

If you are not sure, ask your physician or a pharmacist.

**Do not exceed the recommended dose.**

Swallow the capsules whole with a full glass of water. Do not break, open or chew the hard capsule.

If you have to take multiple capsules, take them as a single dose before going to bed.

This will make you feel less drowsy at other times.

The dosage and treatment will be determined by the physician only. The usual dose for the treatment of newly diagnosed multiple myeloma is 200 mg a day, taken in treatment cycles lasting 4 to 6 weeks, in combination with the following medicines:

- melphalan and prednisolone which are taken on days 1 to 4 of each 6-week cycle.
- dexamethasone which is taken on days 1 to 4, 9 to 12 and 17 to 20 of each 4-week cycle.

For newly diagnosed multiple myeloma patients above 75 years of age taking Thalidomide BMS 50 mg hard capsules in combination with melphalan and prednisone, the recommended starting dose for Thalidomide BMS 50 mg hard capsules is 100 mg per day.

For the treatment of multiple myeloma after failure of other treatments, doses of Thalidomide BMS 50 mg hard capsules from 200 mg a day up to 400 mg a day may be given.

For the treatment of erythema nodosum leprosum, Thalidomide BMS 50 mg hard capsules may be given in doses of 100 to 400 mg a day.

**Tests and Follow-up**

Women of childbearing potential – before starting treatment your physician will perform pregnancy testing and will repeat the test each month during the treatment.

Your physician may perform some tests (blood tests, nerve function tests, etc.) from time to time to make sure the medicine is working and to prevent unwanted side effects.

**If you forgot to take this medicine** at the specified time, and less than 12 hours have passed, take your capsule immediately. Take your next capsule at the usual time.

If more than 12 hours have passed, do not take your capsule. Take your next capsule at the usual time the next day.

If you are not sure what to do, ask your physician or pharmacist.

If you have trouble remembering when to take your medicine, consult your pharmacist.

Comply with the treatment as recommended by the physician.

**If you have taken an overdose, or if a child accidentally swallowed the medicine**, proceed immediately to a doctor or hospital emergency room and bring the package of the medicine with you. Do this even if you don't experience discomfort or symptoms of poisoning.

Complete the full course of treatment as instructed by the physician.

Even if there is an improvement in your health, do not discontinue use of this medicine without consulting your physician.

**Do not take medicines in the dark! Check the label and the dose each time you take your medicine. Wear glasses if you need them.**

**If you have any additional questions regarding the use of the medicine, consult the physician or the pharmacist.**

#### **4. Side effects**

Like all medicines, Thalidomide BMS 50 mg hard capsules can cause side effects in some of the patients. Do not be alarmed by the list of side effects. You may not experience any of them.

Tell your physician or pharmacist as soon as possible if you do not feel well while you are taking Thalidomide BMS 50 mg hard capsules.

**Stop taking Thalidomide BMS 50 mg hard capsules and see a physician immediately or go to a hospital Emergency Room if you notice the following serious side effects:**

- Sudden signs of allergy such as rash, itching or hives on the skin; swelling of the face, lips or tongue or other parts of the body; and/or shortness of breath, wheezing or trouble breathing.
- Severe skin reactions including painful red patches on the skin; blisters; bleeding in the lips, eyes, mouth and nose; and peeling of the skin. You may have a high temperature (fever), chills and muscle ache at the same time. This could be due to rare but severe skin reactions such as Stevens-Johnson Syndrome, Toxic Epidermal Necrolysis and Drug Reaction with Eosinophilia and Systemic Symptoms.

Call the physician immediately or go to the nearest hospital Emergency Room if you notice one of the following serious side effects:

- **Blurred vision; severe headache; weakness or numbness in the face, arm or leg; trouble speaking or understanding; loss of balance.**

This may be due to a stroke which could be a result of blood clots in the blood vessels of your brain.

- **Sudden pain in your chest or difficulty breathing.**

This may be due to a heart attack or 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.

- **Feeling short of breath or getting tired easily after light physical activity, and swollen ankles and feet.**

This could be due to high blood pressure in the lungs or heart failure, a condition where the heart muscle cannot pump blood strongly enough to supply blood throughout the body.

- **Vomiting blood or material that looks like coffee grounds, rectal bleeding, black sticky stools, or bloody diarrhoea.**

These could be signs of bleeding in your gut.

- **Abdominal pain, dark urine, fever, joint pain, loss of appetite, nausea and vomiting, yellowing of the skin and/or eyes.**

These are symptoms of liver failure which, in some cases, may be due to viral Hepatitis B infection. Some cases of Hepatitis B infection may not result in symptoms initially.

- **Numbness, tingling, abnormal coordination or pain in your hands and feet.**

This may be due to nerve damage. It may become very severe, painful and disabling. If you experience such symptoms, contact your physician immediately, who may reduce the dose or discontinue the treatment. This side effect usually happens after you have been taking this medicine for several months but can happen sooner than this. It can also happen some time after treatment has stopped. It may not resolve, or may resolve slowly.

- **Signs of frequent infections such as fever, severe chills, sore throat or mouth ulcers; bleeding or bruising more easily than normal; and fatigue, headaches, shortness of breath, dizziness, and pallor.**

This may be due to low numbers of blood cells in your body. Your physician may monitor your blood cell numbers during treatment with Thalidomide BMS 50 mg hard capsules.

- **Chest pain and dry cough.**

This may be due to a chest infection e.g. pneumonia, or other lung problems.

- **Seizures, fits or convulsions.**

- **Blurred vision, loss of vision 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 be symptoms of a serious and potentially fatal brain condition known as progressive multifocal leukoencephalopathy (**PML**).

The above list includes serious side effects that may require medical attention.

Other side effects:

Tell your physician or pharmacist if you notice any of the following and they worry you:

- Constipation, indigestion, nausea, vomiting, stomach pain, dry mouth
- Rash, dryness of the skin
- Fainting, dizziness, sleepiness, feeling tired, shaking (tremor), headache, blurred vision, difficulty in coordinating movement, loss of balance
- Swelling of hands and feet, feeling generally unwell, feeling weak, feeling cold
- Depression, confusion, mood changes, anxiety
- Low blood pressure; feeling that your head is spinning, making it difficult to stand up and move normally
- Slow heart rate
- Muscle cramps
- Decreased libido, abnormal periods

The above list mainly includes the more common side effects of your medicine.

**If you experience any of the side effects, if one of them gets worse, or if you notice any side effects not listed in this leaflet, please tell your physician or pharmacist.**

Side effects can be reported to the Ministry of Health by clicking on the link “Report Side Effects of Drug Treatment” that appears on the homepage of the Ministry of Health’s website ([www.health.gov.il](http://www.health.gov.il)) which links to an online form for reporting side effects, or by going to the following link: <https://sideeffects.health.gov.il>  
In addition, you can report by emailing the Registration Holder’s Patient Safety Unit at: [drugsafety@neopharmgroup.com](mailto:drugsafety@neopharmgroup.com)

**5. How should I store this medicine?**

Avoid poisoning! This medicine, and all other medicines, must be stored in a closed place out of the reach and sight of children and/or infants, to avoid poisoning.

Do not induce vomiting unless explicitly instructed to do so by a physician!

Do not use the medicine after the expiry date (exp. date) appearing on the package. The expiry date refers to the last day of that month.

Keep out of the reach and sight of children and any other person not directly involved in the treatment.

Store the blister pack in the original carton pack, at a temperature below 25°C, and protect it from light.

Even if kept in their original container and stored as recommended, medicines may be kept for a limited period only.

Please note the expiry date of the medicine! In case of doubt, consult the pharmacist who dispensed the medicine to you.

Do not store different medications in the same package.

## **6. Additional information**

In addition to the active ingredient, this medicine also contains:

Pregelatinized maize starch, Magnesium stearate, Gelatin, Titanium Dioxide, Printing ink.

How does the medicine look and what is the content of the package -

Thalidomide BMS 50 mg hard capsules are white hard capsules marked "Thalidomide BMS 50 mg". The capsules are supplied in a wallet card containing 28 capsules (2 blister packs of 14 capsules each).

**Registration Holder:** Neopharm Ltd., 6 Hashiloach St., P.O.B. 7063, Petah Tikva 49170.

**Manufacturer:**

Bristol Myers Squibb Pharma EEIG  
Dublin, Ireland

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