

## **Thalidomide Pharmion® 50 mg Hard Capsules Consumer Medicine Information**

**Severe life-threatening birth defects:**

**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 drug or could become pregnant within 4 weeks after stopping the drug. Even a single dose can cause severe birth defects.**

### **WHAT IS IN THIS LEAFLET**

This leaflet answers some common questions about Thalidomide Pharmion.

It does not contain all the available information.

It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking Thalidomide Pharmion against the benefits this medicine is expected to have for you.

**If you have any concerns about taking this medicine, ask your doctor or pharmacist.**

**Keep this leaflet with the medicine.** You may need to read it again.

This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.

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.

### **WHAT THALIDOMIDE PHARMION IS USED FOR**

Thalidomide Pharmion contains an active substance called thalidomide. This belongs to a group of medicines known as immuno-modulating agents that work by acting on the cells involved in the body's immune system. The immune system is part of the body's defence which helps to fight illness and infection.

#### ***Treatment of Multiple Myeloma***

Thalidomide Pharmion is used to treat multiple myeloma, a cancer of the bone marrow.

It is used in combination with other medicines, melphalan and prednisone, for the treatment of newly diagnosed multiple myeloma in patients aged over 65 years or patients who cannot receive high dose chemotherapy. It is also used in combination with dexamethasone at the start of high dose chemotherapy treatment or a bone marrow transplant. To find out more about these medicines, please ask your doctor.

Thalidomide Pharmion may also be used for the treatment of multiple myeloma after other treatments have failed.

#### ***Treatment of Skin Symptoms associated with Severe Erythema Nodosum Leprosum (ENL)***

Thalidomide Pharmion 50 mg Hard Capsules are also used for the treatment of the skin symptoms associated with moderate to severe erythema nodosum leprosum (ENL) which can occur if you have

leprosy. Thalidomide can also help to stop the skin symptoms returning.

If you have any questions about how Thalidomide Pharmion works or why this medicine has been prescribed for you please ask your doctor.

## **BEFORE YOU TAKE THALIDOMIDE PHARMION**

Thalidomide Pharmion will only be prescribed to you by a doctor who has experience in medicines used to treat cancers of the blood.

**Follow your doctor's instructions carefully. You will have been given specific instructions by your doctor particularly on the effects of thalidomide on unborn babies. If you have not fully understood these instructions, please ask your doctor again before taking thalidomide. Your doctor will have enrolled you in the *i-access*<sup>®</sup> thalidomide risk management program to ensure that thalidomide is used safely.**

### **Do not take Thalidomide Pharmion:**

- If you are pregnant or think you may be pregnant or are planning to become pregnant, as Thalidomide Pharmion causes birth defects and foetal death.
- If you are able to become pregnant but are unable to follow the necessary pregnancy prevention measures (outlined in the *i-access*<sup>®</sup> thalidomide risk management program).
- If you are allergic to thalidomide or any of the other ingredients of Thalidomide Pharmion (listed at the end of this leaflet). Some of the symptoms of an allergic reaction may include shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body; and/or rash, itching or hives on the skin. If you think you may be allergic, ask your doctor for advice.
- If you are breastfeeding (see more details below).
- If you are under 12 years of age.

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

**Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.** In that case, return it to your pharmacist.

### ***Take special care with Thalidomide Pharmion:***

Talk to your doctor before taking this medicine in the following situations:

#### **For all patients taking Thalidomide Pharmion**

Check with your doctor before taking this medicine if:

- You are at high risk of a blood clot developing in your veins (deep vein thrombosis) or in your lungs (pulmonary embolism).
- 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 nerve damage, such as numbness, tingling or pain in your hands and feet.
- You have a history of seizures.
- You have had surgery in the previous 7 days or have wounds which are healing.

#### **For women taking Thalidomide Pharmion**

Even if your periods have stopped, it is essential to ask your doctor if there is any risk that you could become pregnant.

Do not take Thalidomide Pharmion if you are pregnant. In addition, you should not become pregnant while taking Thalidomide Pharmion but, if you do, you should inform your doctor immediately. If you are a woman of child-bearing potential you should use effective means of contraception which should also be discussed with your doctor. Effective methods of contraception include the following:

- Implant
- Levonorgestrel-releasing intrauterine system (IUS)
- Medroxyprogesterone acetate depot
- Tubal sterilisation
- 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).

These birth control methods must be used for at least 4 weeks before starting Thalidomide Pharmion treatment, during treatment, during treatment interruption, and for at least 4 weeks after Thalidomide Pharmion treatment has stopped.

Your doctor will tell you what method of contraception to use.

#### **For men taking Thalidomide Pharmion**

Thalidomide passes into semen. Therefore do not have unprotected intercourse. You should use barrier methods of contraception (e.g. condoms) if your partner is of child-bearing potential and for 4 weeks after treatment has stopped. You must not donate semen during treatment or for 4 weeks after stopping treatment.

#### ***Donating Blood:***

You must not donate blood during Thalidomide Pharmion treatment and for 4 weeks after stopping treatment.

If you are not sure if any of the above apply to you, talk to your doctor before taking Thalidomide Pharmion.

#### ***Taking other medicines:***

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines since other medicines could interfere with the effect of thalidomide. This includes medicines obtained without a prescription from a pharmacy, supermarket or health food shop.

Make sure you tell your doctor if you are taking any medicines which cause sleepiness as thalidomide may increase their effects.

#### ***Children:***

Thalidomide Pharmion is not to be taken by children under 12 years of age.

#### ***Taking Thalidomide Pharmion with food and drink:***

Thalidomide Pharmion should be taken at least one hour after food.

Do not drink alcohol while you are taking Thalidomide Pharmion. This is because alcohol can make you sleepy and Thalidomide Pharmion can make you even sleepier.

#### ***Pregnancy:***

Thalidomide causes severe birth defects or death to an unborn baby.

- As little as one capsule taken by a pregnant woman can cause a baby to have serious birth defects.
- These defects can include shortened arms or legs, malformed hands or feet, eye or ear defects, and problems with internal organs.

If you are pregnant, you must not take Thalidomide Pharmion. In addition, you must not become pregnant while taking Thalidomide Pharmion.

You must use an effective method of contraception if you are a woman who is able to become pregnant (see previous section, “Take special care with Thalidomide Pharmion”).

***You must stop treatment and inform your doctor straight away if:***

- You miss or think you have missed a period, or you have unusual menstrual bleeding, or suspect you are pregnant.
- You have heterosexual intercourse without using an effective method of contraception.

For men taking Thalidomide Pharmion who have a female partner who is able to become pregnant, please see previous section “Take special care with Thalidomide Pharmion”. If your partner becomes pregnant whilst you are taking Thalidomide Pharmion, you should inform your doctor immediately.

***Breast-feeding:***

It is not known if thalidomide is passed into breast milk. Therefore, do not breastfeed while you are receiving Thalidomide Pharmion.

***Use in other cases:***

No specific dose adjustments are recommended for the elderly or for patients with impaired renal or hepatic function. However you should tell your doctor if you have or have had any problems with your kidney or liver.

***Driving and using machines:***

Do not drive or use any tools or machines if you experience side effects, such as dizziness, tiredness, sleepiness or blurred vision.

***Important information about some of the ingredients of Thalidomide Pharmion:***

Thalidomide Pharmion contains lactose (a type of sugar). Therefore Thalidomide Pharmion should not be taken by patients with rare hereditary problems of glucose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption.

## **HOW TO TAKE THALIDOMIDE PHARMION**

Always take Thalidomide Pharmion exactly as your doctor has told you to. You should check with your doctor if you are not sure.

***How much to take:***

Your doctor will choose the dose for you, monitor your progress and may adjust your dose. Your doctor will tell you how to take Thalidomide Pharmion and for how long you will need to take it.

For newly diagnosed multiple myeloma, the usual dose is 200 mg (4 capsules) a day, taken in treatment cycles lasting 4 to 6 weeks, in combination with the following drugs:

- 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 the treatment of multiple myeloma after failure of other treatments, doses of Thalidomide Pharmion from 200 mg a day up to 400 mg a day may be given.

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

***Taking this medicine:***

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

***If you forget to take Thalidomide Pharmion:***

**If you forget to take Thalidomide Pharmion at your regular time and**

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

If you have trouble remembering when to take your medicine, ask your pharmacist for some hints.

***If you take too much Thalidomide Pharmion (overdose):***

Immediately telephone your doctor or the National Poisons Centre (telephone 0800 POISON or 0800 764 766) or go to Accident and Emergency at your nearest hospital, if you think that you or anyone else may have taken too much Thalidomide Pharmion. Do this even if there are no signs of discomfort or poisoning. Keep the telephone numbers for these places handy.

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

**WHILE YOU ARE TAKING THALIDOMIDE PHARMION**

Thalidomide Pharmion is available under a restricted distribution program called the *i-access*<sup>®</sup> thalidomide risk management program. Only physicians and pharmacists registered with this program can prescribe and dispense the product. In addition, Thalidomide Pharmion will only be given to patients who are registered and meet all the conditions of the program.

***Things you must do:***

Tell any other doctors, dentists, and pharmacists who are treating you that you are taking Thalidomide Pharmion.

If you are about to be started on any new medicine, tell your doctor, dentist or pharmacist that you are taking Thalidomide Pharmion.

If you become pregnant while taking Thalidomide Pharmion tell your doctor immediately.

***Things you must not do:***

Do not stop taking Thalidomide Pharmion or change the dose without first checking with your doctor.

Do not let yourself run out of medicine over the weekend or on holidays.

Do not give Thalidomide Pharmion to anyone else, even if they have the same condition as you.

Do not take Thalidomide Pharmion to treat any other complaints unless your doctor or pharmacist tells you to.

## **SIDE EFFECTS**

Like all medicines, Thalidomide Pharmion can cause side effects though not everyone gets them. The following side effects may happen with this medicine:

***Stop taking Thalidomide Pharmion and see a doctor straight away if you notice the following serious side effects – you may need urgent medical treatment:***

- Severe skin reactions including rashes and blistering of the skin and mucosa. You may have a high temperature at the same time.

***Tell your doctor straight away if you notice any of the following serious side effects:***

- **• Numbness, tingling, abnormal co-ordination 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, speak to your doctor 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 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.

Other side effects include:

- 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 Pharmion.
- 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).

Additional side effects have been reported after this medicine was marketed. These include

- very serious skin reaction (toxic epidermal necrolysis)
- underactive thyroid (hypothyroidism)
- bowel obstruction
- sexual dysfunction, for example impotence
- Tumour Lysis Syndrome – this refers to complications caused by the breakdown products of dying cancer cells. Your doctor will monitor you for these complications and may suggest appropriate precautions.

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 immediately.

## **AFTER TAKING THALIDOMIDE PHARMION**

### ***How to store Thalidomide Pharmion:***

- Keep Thalidomide Pharmion out of the reach and sight of children.
- Do not use Thalidomide Pharmion after the expiry date, which is stated on the blister after ‘EXP’. The expiry date refers to the last day of that month.
- Do not use any pack that is damaged or shows signs of tampering.
- Store below 25°C.
- Store in the original package.

### ***Disposal:***

Medicines should not be disposed of via wastewater or household waste. Any unused Thalidomide Pharmion must be returned to your pharmacist. These measures will help to protect the environment.

## **PRODUCT DESCRIPTION**

### ***What Thalidomide Pharmion looks like:***

Thalidomide Pharmion 50 mg Hard Capsules are white hard capsules marked “Thalidomide 50 mg Pharmion” with a “Do not get pregnant” symbol.

Thalidomide Pharmion 50 mg Hard Capsules are supplied in boxes containing 2 blister strips each containing 14 capsules.

### ***What Thalidomide Pharmion contains:***

- The active substance is thalidomide.
- Other ingredients are anhydrous lactose, microcrystalline cellulose, povidone, stearic acid, anhydrous silica, and crospovidone.
- The capsule shells contain gelatin and titanium dioxide (E171). The printing ink is composed of shellac and black iron oxide (E172).

**SPONSOR**

Thalidomide Pharmion is supplied in New Zealand by:  
Douglas Pharmaceuticals  
Central Park Drive, Lincoln  
PO Box 45 027  
Auckland 0651  
PH: (09) 835 0660.

**Date of preparation:** This leaflet was prepared in November 2010.