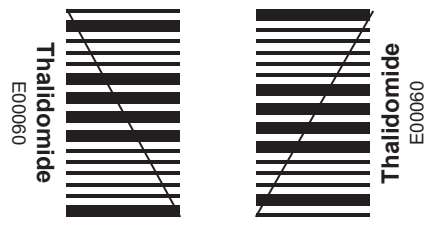
Pharmacode position may change as per Supplier's m/c requirement & additional small pharma code may appear on the front / back panel



Package leaflet: Information for the user

Thalidomide 50 mg capsules, hard

thalidomide

WARNING
Thalidomide causes birth defects and foetal death. Do not take thalidomide if you are pregnant or could become pregnant. You must follow the contraception advice given to you by your doctor.

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet
1. What Thalidomide is and what it is used for
2. What you need to know before you take Thalidomide
3. How to take Thalidomide
4. Possible side effects
5. How to store Thalidomide
6. Contents of the pack and other information

1. What is Thalidomide is and What Thalidomide is used for

What is Thalidomide is
Thalidomide contains an active substance called thalidomide. This belongs to a group of medicines which affect how your immune system works.

What Thalidomide is used for
Thalidomide is used with two other medicines called 'melphalan' and 'prednisone' to treat adults with a type of cancer called multiple myeloma. It is used in people who have recently been diagnosed and who have not been prescribed another medicine for their multiple myeloma before who are aged 65 years and over or aged less than 65 years who cannot be treated with high dose chemotherapy, which can be very difficult for the body to handle.

What is multiple myeloma
Multiple myeloma is a type of cancer which affects a certain type of white blood cell, called the plasma cell. These cells collect in the bone marrow and divide out of control. This can damage the bone and kidneys. Multiple myeloma generally cannot be cured. However, the signs and symptoms can be greatly reduced or disappear for a period of time. This is called a 'remission'.

How Thalidomide works
Thalidomide works by helping the body's immune system and directly attacking the cancer. It works in a number of different ways:
- by stopping the cancer cells developing
- by stopping blood vessels growing in the cancer
- by stimulating part of the immune system to attack the cancer cells

2. What you need to know before you take Thalidomide

You will have been given specific instructions by your doctor, particularly on the effects of thalidomide on unborn babies (outlined in the Thalidomide Pregnancy Prevention Programme).

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. See also further information in this section under "Warnings and precautions" and "Pregnancy and breast-feeding".

Do not take Thalidomide
- if you are pregnant or think you may be pregnant or are planning to become pregnant, **as Thalidomide causes birth defects and foetal death.**
- if you are able to become pregnant, unless you are able to follow or comply with the required contraceptive measures to prevent you from becoming pregnant (see section 2 "Warnings and precautions" and "Pregnancy and breast-feeding").
- 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 allergic to thalidomide or any of the other ingredients of this medicine listed in section 6 "Contents of the pack and other information"

Do not take Thalidomide if any of the above applies to you. If you are not sure, talk to your doctor or pharmacist before taking Thalidomide.

Warnings and precautions
Talk to your doctor, pharmacist, or nurse before taking this medicine in the following situations.

For women taking Thalidomide
Before starting the treatment, you should ask your doctor if you are able to become pregnant, even if you think this is unlikely. Even if you do not have a menstrual bleeding following cancer therapy, you may become pregnant.
If you are able to become pregnant:
- Your doctor will make sure that you have pregnancy tests
  - o before treatment
  - o every 4 weeks during treatment
  - o 4 weeks after stopping treatment
- You must use one effective method of contraception:
  - o for at least 4 weeks before starting treatment
  - o during treatment
  - o until at least 4 weeks after stopping treatment

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

If you can become pregnant, your doctor will record with each prescription that the necessary measures, as outlined above, have been taken.

For men taking Thalidomide
Thalidomide passes into semen. Therefore, do not have unprotected intercourse, even if you had a vasectomy.
- Pregnancy and any exposure during pregnancy must be avoided. Always use a condom:
  - o during treatment
  - o for at least 7 days after stopping treatment
- You must not donate semen:
  - o during treatment
  - o for at least 7 days after stopping treatment

For all patients
Talk to your doctor before taking Thalidomide if
- 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 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 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 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 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, 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 (see also section 4 "Possible side effects"). You must not donate blood during Thalidomide treatment and for at least 7 days after stopping treatment.

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

Children and adolescents
Thalidomide is not recommended for use in children and young people under 18 years.

Other medicines and Thalidomide
Tell your doctor or pharmacist if you are taking or have recently taken any other medicines. This includes medicines obtained without a prescription, including herbal medicines.

Make sure you tell your doctor if you are taking any medicines which:
- cause sleepiness as thalidomide may increase their effects. This includes sedatives (such as
- anxiolytics, hypnotics, antipsychotics, H1 antihistamines, opiate derivatives and barbiturates).
- slow the heart rate (induce bradycardia, such as anticholinesterases and beta blockers).
- 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.

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

Pregnancy and breast-feeding
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

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. In addition, you must not become pregnant while taking Thalidomide.

You must use one effective method of contraception if you are a woman who is able to become pregnant (see section 2, "What you need to know before you take Thalidomide").

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.

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

For men taking Thalidomide who have a female partner who is able to become pregnant, please see section 2 "What you need to know before you take Thalidomide". If your partner becomes pregnant whilst you are taking thalidomide, you should inform your doctor immediately.

Breast-feeding
Do not breastfeed when taking Thalidomide as it is not known if thalidomide is passed into human breast milk.

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.

Thalidomide capsules, hard contain isomalt
If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

Information on sodium content
This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

3. How to take Thalidomide

Always take Thalidomide exactly as your doctor or pharmacist has told you to. Check with your doctor or pharmacist if you are not sure.

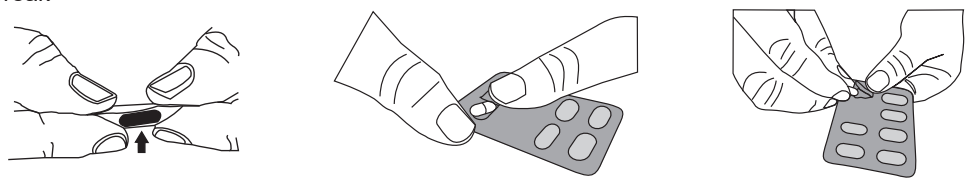
How much to take
The recommended dose is 200 mg (4 x 50 mg capsules) a day for adults aged 75 years and under or 100 mg (2 x 50 mg capsules) a day for adults aged over 75 years. However, your doctor will choose the dose for you, monitor your progress and may adjust your dose. Your doctor will tell you how to take Thalidomide and for how long you will need to take it (see section 2, "What you need to know before you take Thalidomide").

Thalidomide is taken daily in treatment cycles, each cycle lasting 6 weeks, in combination with melphalan and prednisone which are taken on days 1 to 4 of each 6-week cycle.

Taking this medicine
- Do not break, open or chew the capsules. If powder from a broken Thalidomide capsule makes contact with the skin, wash the skin immediately and thoroughly with soap and water.
- Healthcare professionals, caregivers and family members should wear disposable gloves when handling the blister or capsule. Gloves should then be removed carefully to prevent skin exposure, placed in a sealable plastic polyethylene bag and disposed of in accordance with local requirements. Hands should then be washed thoroughly with soap and water. Women who are pregnant or suspect they may be pregnant should not handle the blister or capsule.

- 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.

To remove the capsule from the blister, press only one end of the capsule out to push it through the foil. Do not apply pressure on the centre of the capsule as this can cause it to break



If you take more Thalidomide than you should
If you take more Thalidomide than you should, talk to a doctor or go to a hospital straightaway. If possible, take the medicine pack and this leaflet with you.

If you forget to take Thalidomide
If you forget to take Thalidomide at your regular time and
- less than 12 hours have passed: take your capsules immediately.
- more than 12 hours have passed: do not take your capsules. Take your next capsules at the usual time the next day.

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

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

The following side effects may happen with this medicine:

Stop taking Thalidomide and see a doctor straight away if you notice the following serious side effects – you may need urgent medical treatment:
- Extremely intense and serious skin reactions. The adverse reaction of the skin may appear as rashes with or without blisters. Skin irritation, sores or swelling in the mouth, throat, eyes, nose and around the genitals, oedema and fever and flulike symptoms may occur. These symptoms may be signs of the rare and serious skin reactions Stevens-Johnson syndrome, toxic epidermal necrolysis or DRESS syndrome.
- Allergic reactions such as a localised or generalised pruritic rash, angioedema and anaphylactic reaction (serious types of allergic reaction that may be manifested as hives, rashes, swelling of eyes, mouth or face, difficulty of breathing, or itching)

Tell your doctor straight away if you notice any of the following serious side effects:
- **Numbness, tingling, abnormal coordination or pain in your hands and feet.** This may be due to nerve damage (called 'peripheral neuropathy'), which is a very common side effect.
  It may become very severe, painful and disabling. If you experience such symptoms, speak to your doctor straight away, 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 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 clot in the arteries leading to your lungs (called 'pulmonary embolism'), which is a common side effect. 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 (deep vein thrombosis), which is a common side effect. These can happen during treatment, or after treatment has stopped.
- **Chest pain spreading to the arms, neck, jaw, back or stomach, feeling sweaty and breathless, feeling sick or vomiting.** These may be symptoms of a heart attack/ myocardial infarction (which may be due to blood clots in the arteries of your heart).
- **Having difficulty in seeing or speaking, which is temporary.** These may be symptoms of a stroke (which may be due to a clot in an artery in your brain).
- **Fever, chills, sore throat, cough, mouth ulcers or any other symptoms of infection.**
- **Bleeding or bruising in the absence of injury.**

Other side effects include:
It is important to note that a small number of patients with multiple myeloma may develop additional types of cancer, especially haematological malignancies, and it is possible that this risk may be increased with Thalidomide treatment; therefore, your doctor should carefully evaluate the benefit and risk when you are prescribed Thalidomide.

Very common (may affect more than 1 in 10 people)
- Constipation.
- Feeling dizzy.
- Sleepiness, feeling tired.
- Shaking (tremor)
- Decreased or abnormal sensation (dysaesthesia).
- Swelling of hands and feet.
- 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.

Common (may affect up to 1 in 10 people)
- Indigestion, feeling sick (nausea), being sick (vomiting), dry mouth.
- Rash, dryness of the skin.
- A fall in the number of white blood cells (neutropenia) accompanied by fever and infection.
- A fall in the number of red and white blood cells and platelets at the same time (pancytopenia)
- Feeling weak, faint or unsteady, lack of energy or strength, low blood pressure.
- Fever, feeling generally unwell.
- Convulsions.
- A spinning feeling in your head, making it difficult to stand up and move normally.
- Blurred vision.
- Chest infection (pneumonia), lung disease.
- A slow heart rate, heart failure.
- Depression, confusion, mood changes, anxiety.
- Hearing decreased or deafness
- Kidney disease (renal failure).

Uncommon (may affect up to 1 in 100 people)
- Inflammation and swelling of the tubes in your lungs (bronchitis).
- Inflammation of the cells lining your stomach wall.
- A hole in part of your large bowel (colon) which can cause infection
- Bowel obstruction.
- Fall of blood pressure on standing which may lead to fainting
- Irregularities of the heartbeat (heart block or atrial fibrillation), feeling faint or fainting.

Not known (frequency cannot be estimated from the available data):
- Underactive thyroid (hypothyroidism).
- Sexual dysfunction, for example impotence.
- Severe blood infection (sepsis) accompanied by fever, chills and severe shaking, and possibly complicated by low blood pressure and confusion (septic shock).
- Tumour Lysis Syndrome - metabolic complications that can occur during the treatment of cancer and sometimes even without treatment. These complications are caused by the break-down products of dying cancer cells and may include the following: changes to blood chemistry; high potassium, phosphorus, uric acid, and low calcium consequently leading to changes in kidney function, heartbeat, seizures, and sometimes death.
- Injury to the liver (hepatic disorder) including abnormal liver test results
- Bleeding from the stomach or bowels (gastrointestinal haemorrhage).
- Worsening of Parkinson's disease symptoms (such as tremor, depression, or confusion)
- Pain in the upper abdomen and/or back, which may be severe, and which remains for few days, possibly accompanied by nausea, vomiting, fever and a rapid pulse – these symptoms may be due to the inflammation of the pancreas (pancreatitis).
- Increase in blood pressure within blood vessels that supply the lungs which can lead to shortness of breath, tiredness, dizziness, pain in the chest, a faster heartbeat, or swelling in the legs or ankles (pulmonary hypertension).
- Viral infections, including herpes zoster (also known as 'shingles', a viral disease that causes a painful skin rash with blisters) and recurrence of hepatitis B infection (which can cause yellowing of the skin and eyes, dark brown-coloured urine, right-sided stomach pain, fever and feeling nauseous or being sick).
- A brain condition with symptoms including vision changes, headache, seizures, and confusion, with or without high blood pressure (Posterior Reversible Encephalopathy Syndrome or PRES).
- A condition affecting the skin caused by inflammation of small blood vessels, along with pain in the joints and fever (leukocytoclastic vasculitis).

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme, Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Thalidomide

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the wallet card and the blister after EXP. The expiry date refers to the last day of that month.

Do not use if you notice any damage or signs of tampering.

*Clear PVC/Aclar(PCTFE) - Aluminium foil blister pack: "*This medicinal product does not require any special storage conditions"

Clear PVC/PVdC - Aluminium foil blister pack: "Store below 30°C".

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

6. Contents of the pack and other information

What Thalidomide capsules, hard contain
- The active substance is thalidomide. Each capsule, hard contains 50 mg of thalidomide.
- The other ingredients are:
  - o The capsule fill contains isomalt, croscarmellose sodium, talc, and sodium stearyl fumarate.
  - o The capsule shell contains gelatin and titanium dioxide (E171).
  - o The printing ink is composed shellac, black iron oxide (E172), and potassium hydroxide.

What Thalidomide capsules, hard look like and contents of the pack
Thalidomide capsules, hard are white colour powder filled in size "4" hard gelatin capsule with white opaque cap imprinted with "TLM" in black ink and white opaque body imprinted with "50" in black ink. Each capsule measures approximately 14.00 mm x 5.30 mm

Thalidomide 50 mg Capsules, Hard are available in blister pack (i.e., Clear PVC/Aclar *(PCTFE)* - Aluminium foil blister & Clear PVC/PVdC - Aluminium foil blister).

Pack size: 28 hard capsules

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This leaflet was last revised in 06/2026.

Ref: Ver 3.0

E00060