Thalidomide Pregnancy Prevention Programme

Information for Women of Non Childbearing Potential

This brochure contains information about:

- **Preventing harm to unborn babies:** If thalidomide is taken during pregnancy it can cause severe birth defects or death to an unborn baby.
- **Other side effects of thalidomide:** These include severe heart disease
- **Thalidomide Pregnancy Prevention Programme:** This Programme is designed to prevent unborn babies being exposed to thalidomide.

This brochure provides education on thalidomide and it will ensure that you know what to do before, during and after taking thalidomide.

Please read this brochure carefully. If you do not understand something, please ask your prescriber to explain it.

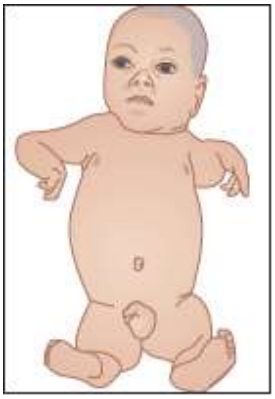
Introduction

Thalidomide belongs to a group of medicines known as 'immunosuppressive' medicines. These work by acting on the cells involved in your immune system. The immune system is part of the body's defence which helps to fight illness and infection. Thalidomide also has anti-angiogenic properties. This means that it prevents the development of new blood vessels (angiogenesis). Angiogenesis is important for cancers because they need to produce new blood vessels in order to grow. Thalidomide was investigated in cancer to see whether it would stop cancer growing by preventing the development of new blood vessels.

Thalidomide is approved in the European Union for the treatment of multiple myeloma (cancer of the plasma cells in the bone marrow) in combination with melphalan and prednisone.

The information leaflet which came with your medicine tells you more about thalidomide.

This brochure is part of the "Thalidomide Pregnancy Prevention Programme", which is necessary because if thalidomide is taken during pregnancy it can cause severe birth defects or death to an unborn baby. In the 1950s and 1960s thalidomide was prescribed to pregnant women as a sedative and to relieve morning sickness. As a result approximately 12,000 children were born with severe birth defects caused by thalidomide, and approximately 5,000 are alive today.



The Thalidomide Pregnancy Prevention Programme is designed to prevent unborn babies being exposed to thalidomide. It makes sure you know what to do before, during and after taking the medicine:

- Thalidomide can cause severe birth defects or death to an unborn baby
- Birth defects may include shortened arms or legs, malformed hands or feet, eye or ear defects, and internal organ problems

This brochure contains important information about the Thalidomide Pregnancy Prevention Programme. You must read the information carefully, and before starting your treatment you should:

- Understand the risks of thalidomide treatment.
- Understand the instructions for taking thalidomide safely.
- Understand what to expect during your initial and follow-up consultations with your prescriber.
- Please make sure that you understand what your prescriber has told you before starting thalidomide.
- **If you don't understand something, please ask your prescriber to explain it again.**

Thalidomide and Birth Defects

All medicines can cause unwanted effects or 'side effects'. The most important side effect of thalidomide is that if taken during pregnancy, it can cause severe birth defects or death to an unborn baby. The birth defects include shortened arms or legs, malformed hands or feet, eye or ear defects, and internal organ problems. This means thalidomide must never be taken by:

- Women who are pregnant
- Women who could become pregnant unless they follow the Thalidomide Pregnancy Prevention Programme.

Thalidomide and Other Possible Side Effects

Like all medicines, thalidomide can cause side effects although not everybody gets them. Some side effects are more common than others and some are more serious than others. Ask your prescriber or pharmacist if you would like more information and refer to the Package Leaflet. Almost all side effects are temporary and can be easily prevented or treated. The most important thing is to be aware of what to expect and what to report to your prescriber. It is important that you talk to your prescriber if you have any side effects during thalidomide treatment.

Stop taking thalidomide and see a doctor straight away if you notice the following symptoms: palpitations, chest pain, pressure in the chest, difficulty in breathing, sweating, light headedness, dizziness, blurred vision, and fatigue. This is important because the above-mentioned symptoms may be indicators of more severe heart disease which may need urgent medical attention.

Thalidomide Treatment

Before starting treatment your prescriber will ask you to read and sign a *Treatment Initiation Form* , which confirms that while taking thalidomide:

- You understand the risks of birth defects
- You understand the other important safety messages that must be followed.

Your prescriber will keep this form with your medical records, and you will be given a copy.

Contraceptive Methods

Your prescriber understands that you are not able to have children, because:

- You are at least 50 years old and it has been at least one year since your last period. If your periods have stopped because of cancer therapy, then there is a chance you could become pregnant and you will need to follow the contraceptive advice
- Your womb has been removed (hysterectomy)
- Your fallopian tubes and both ovaries have been removed (bi-lateral salpingo-oophorectomy)
- You have premature ovarian failure, confirmed by a specialist gynaecologist
- You have the XY genotype, Turner's syndrome or uterine agenesis

If you believe that you are a woman of childbearing potential then please inform your prescriber straight away, as you must read the brochure for Women of Childbearing Potential.

Additional Safety Measures

- Please remember that your thalidomide must only be used by you. Do not share your medicine with anyone else, even if they have similar symptoms to you.
- Store your thalidomide capsules safely, so no one else could take them by accident.
- Keep thalidomide out of reach and sight of children.
- You must not donate blood while you are being treated with thalidomide (including dose interruptions), and for at least 7 days after stopping treatment.

Receiving Your Prescription

Your prescriber will write a prescription for no more than 12 weeks supply, and you will need to see your prescriber each time you need a repeat prescription.

End of Treatment

After completing your thalidomide treatment, it is important that:

- You return any unused thalidomide capsules to your pharmacist.
- You do not donate blood for at least 7 days.

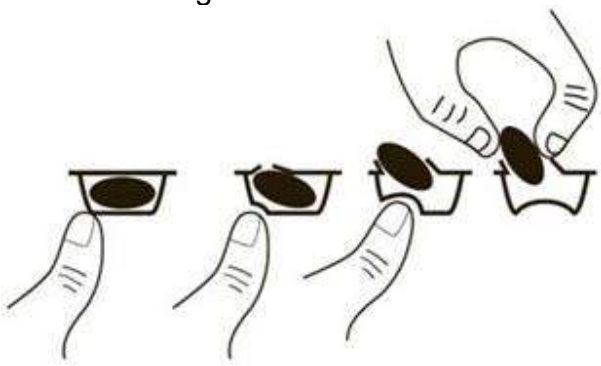
Points to Consider for Handling the Medicinal Product: for Patients, Family Members and Caregivers

Keep the blisters with the capsules in the original pack.

Capsules can occasionally become damaged when pressing them out of the blister, especially when the pressure is put onto the middle of the capsule. Capsules should not be pressed out of the blister by putting pressure on the middle nor by putting pressure on both ends as this can result in deformation and breaking of the capsule.

It is recommended to press only on one site at the end of the capsule (see figure below) as therefore the pressure is located to one site only which reduces the risk of capsule deformation or breakage.

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. Refer below for further guidance.



When handling the medicinal product use the following precautions to prevent potential exposure if you are a family member and/or caregiver

- If you are a woman who is pregnant or suspect that you may be pregnant, you should not handle the blister or capsule.
- Wear disposable gloves when handling product and or packaging (i.e., blister or capsule).
- Use proper technique when removing gloves to prevent potential skin exposure (see below).

- Place gloves in sealable plastic polyethylene bag and dispose according to local requirements.
- Wash hands thoroughly with soap and water after removing gloves.
- Patients should be advised never to give thalidomide to another person.

If a drug product package appears visibly damaged, use the following extra precautions to prevent exposure

- If outer carton is visibly damaged – **Do Not Open**.
- If blister strips are damaged or leaking or capsules are noted to be damaged or leaking – **Close Outer Carton Immediately**.
- Place the product inside a sealable plastic polyethylene bag.
- Return unused pack to the pharmacist for safe disposal as soon as possible.

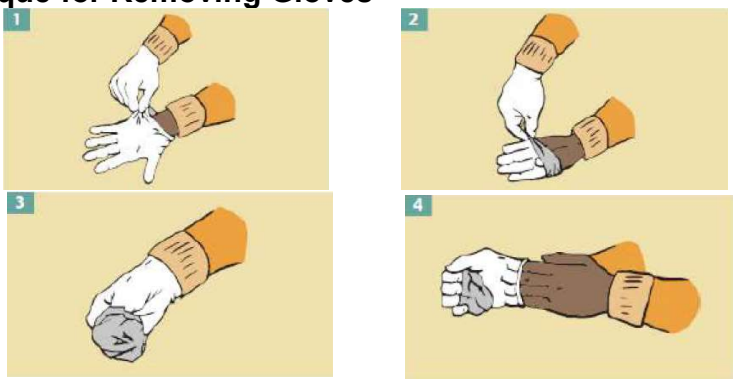
If product is released or spilled, take proper precautions to minimise exposure by using appropriate personal protection

- If capsules are crushed or broken, dust containing drug substance may be released. Avoid dispersing the powder and avoid breathing the powder.
- Wear disposable gloves to clean up the powder.
- Place a damp cloth or towel over the powder area to minimise entry of powder into the air. Add excess liquid to allow the material to enter solution. After handling, clean the area thoroughly with soap and water and dry it.
- Place all contaminated materials including damp cloth or towel and the gloves into a sealable polyethylene plastic bag and dispose in accordance with local requirements for medicinal products.
- Wash your hands thoroughly with soap and water after removing the gloves.
- Please report to the prescriber and/or pharmacist immediately.

If the contents of the capsule are attached to the skin or mucous membranes

- If you touch the drug powder, please wash exposed area thoroughly with running water and soap.
- If your eye had contact with the powder, if worn and if easy to do, remove contact lenses and discard them. Immediately flush eyes with copious quantities of water for at least 15 minutes. If irritation occurs please contact an ophthalmologist.

Proper Technique for Removing Gloves



- Grasp outside edge near wrist (1).
- Peel away from hand, turning glove inside-out (2).
- Hold in opposite gloved hand (3).
- Slide ungloved finger under the wrist of the remaining glove, be careful not to touch the outside of the glove (4).
- Peel off from inside, creating a bag for both gloves.
- Discard in appropriate container.
- Wash your hands with soap and water thoroughly

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Personal Notes

Please use this space to write down any questions for your prescriber for discussion at your next appointment.

▼***This medicinal product is subject to additional monitoring. Healthcare professionals are asked to report any suspected adverse reactions via www.medicinesauthority.gov.mt/adrportal***

Further Information

Further information regarding your thalidomide treatment can be obtained from the following organisations:

- International Myeloma Foundation **www.myeloma.org**
- Myeloma Euronet **www.myeloma-euronet.org**
- Myeloma UK **www.myelomaonline.org.uk**