Thalidomide Celgene® Pregnancy Prevention Programme

Information for Women of Non Childbearing Potential Taking Thalidomide Celgene®

Warning:

Severe life-threatening birth defects. If Thalidomide Celgene® is taken during pregnancy it can cause severe birth defects or death to an unborn baby. Thalidomide Celgene® must never be used by women who are pregnant, as just one capsule can cause severe birth defects. Thalidomide Celgene® must never be used by women who are able to become pregnant unless they follow the Thalidomide Celgene® Pregnancy Prevention Programme.

This booklet contains information about:

- **Preventing harm to unborn babies:** If Thalidomide Celgene® is taken during pregnancy it can cause severe birth defects or death to an unborn baby.

- **Other side effects of Thalidomide Celgene®:** These include nerve damage, blood clots in your veins or arteries, severe skin problems.

- **Thalidomide Celgene® Pregnancy Prevention Programme:** This Programme is designed to make sure that unborn babies are not exposed to Thalidomide Celgene®. It will provide you with information about what to expect from your treatment, and explain the risks and your responsibilities.

This booklet will help you understand these problems and make sure you know what to do before, during and after taking Thalidomide Celgene®.

For your own health and safety, please read this booklet carefully. If you do not understand something, please ask your doctor to explain it again.

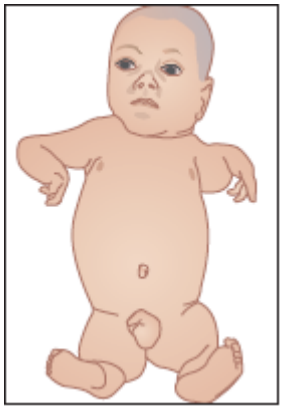
Introduction

Thalidomide Celgene® 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 Celgene® 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 Celgene® was investigated in cancer to see whether it would stop cancer growing by preventing the development of new blood vessels.

A large number of trials have shown the benefits of Thalidomide Celgene® in multiple myeloma (cancer of the plasma cells in the bone marrow). Thalidomide Celgene® is approved in the European Union for the treatment of this cancer in combination with melphalan and prednisone.

The information leaflet which came with your medicine tells you more about Thalidomide Celgene®.

This booklet is part of the "Thalidomide Celgene® Pregnancy Prevention Programme", which is necessary because if Thalidomide Celgene® 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 Celgene® Pregnancy Prevention Programme is designed to make sure that unborn babies are not exposed to Thalidomide Celgene®. It makes sure you know what to do before, during and after taking the medicine:

- Thalidomide Celgene® 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 booklet contains important information about the Thalidomide Celgene® Pregnancy Prevention Programme. You must read the information carefully, and before starting your treatment you should:

- Understand the risks of Thalidomide Celgene® treatment.

- Understand the guidelines for taking Thalidomide Celgene® safely.
- Understand what to expect during your initial and follow-up consultations with your doctor.

Your doctor will have explained to you the risks of Thalidomide Celgene® treatment, and specific instructions that you must follow.

- Please make sure that you understand what your doctor has told you before starting Thalidomide Celgene®.
- **If you don't understand something, please ask your doctor to explain it again.**

Thalidomide Celgene® and Birth Defects

All medicines can cause unwanted effects or 'side effects'. The most important side effect of Thalidomide Celgene® 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 Celgene® must never be taken by:

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

Thalidomide Celgene® and Other Possible Side Effects

Like all medicines, Thalidomide Celgene can cause side effects although not everybody gets them. It is important that you talk to your doctor if you have any side effects from Thalidomide Celgene® treatment.

Stop taking Thalidomide Celgene® and see a doctor straight away if you notice the following serious side effect, as you may need urgent medical treatment:

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

See a doctor straight away if you notice any of the following serious side effects:

- **Numbness, tingling, or pain in your hands and feet**. This may be due to nerve damage (called 'peripheral neuropathy'), which 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
- **Chest pain spreading to the arms, neck, jaw, back or stomach, feeling sweaty** and **breathless, feeling sick** or **vomiting.** This may be due to blood clots in the arteries, (which may be symptoms of a heart attack/myocardial infarction).
- Sudden **pain in your chest** or difficulty in breathing. This may be due to blood clots in the artery leading to your lungs (called 'pulmonary embolism'), which 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). These can happen during treatment, or after treatment has stopped

Other side effects may include:

- Feeling weak, faint or unsteady, lack of energy or strength, low blood pressure (syncope)
- A slow heart rate, heart failure (bradycardia)
- Irregularities of the heartbeat (heart block or atrial fibrillation), feeling faint or fainting (syncope)
- Sleepiness, feeling tired (somnolence)

Section 4 of the patient information leaflet which is provided with your medicine tells you more about the possible Thalidomide Celgene® side effects.

Reporting of Adverse Reactions
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in the package leaflet. You should also report side effects directly via the national reporting system to
ADR Reporting,The Medicines Authority, Post-Licensing Directorate,
Sir Temi Zammit Buildings, Malta Life Sciences Park,
San Gwann SGN 3000, Malta
Website: www.medicinesauthority.gov.mt
e-mail: postlicensing.medicinesauthority@gov.mt
OR
ADR Reporting: www.medicinesauthority.gov.mt/adrportal

By reporting side effects you can help provide more information on the safety of this medicine.

Thalidomide Celgene® Treatment

Before Starting
Your doctor will talk to you about what to expect from your treatment, and explain the risks and your responsibilities. If there is anything you do not understand, please ask your doctor to explain it again.

Before starting treatment your doctor will ask you to read and sign a 'Treatment Initiation Form', which confirms that while taking Thalidomide Celgene®:

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

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

Pregnancy Prevention

Your doctor 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 or breast feeding, then there is a chance you could become pregnant and you will need to follow the pregnancy prevention 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
- You are a child over 8 years old who is not yet able to become pregnant (advice for parent/guardian)

If you believe that you are a woman of childbearing potential then please inform your doctor straight away, as you must read the booklet called 'Information for Women of Childbearing Potential and their Partners Taking Thalidomide Celgene®'.

Safety Measures

You must follow a number of important safety measures when taking Thalidomide Celgene®.

- Please remember that your Thalidomide Celgene® 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 Celgene® capsules safely, so no one else could take them by accident.
- Keep Thalidomide Celgene® out of reach and sight of children.
- You must not donate blood while you are being treated with Thalidomide Celgene®, and for one week after stopping treatment.

Receiving Your Prescription

When your doctor writes your prescription they will also provide you with a 'Patient Card' that must be provided to the pharmacist, which confirms that all of the Thalidomide Celgene® Pregnancy Prevention Programme measures have been followed. Your pharmacist will ask to review the 'Patient Card' prior to dispensing your Thalidomide Celgene®.

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

End of Treatment

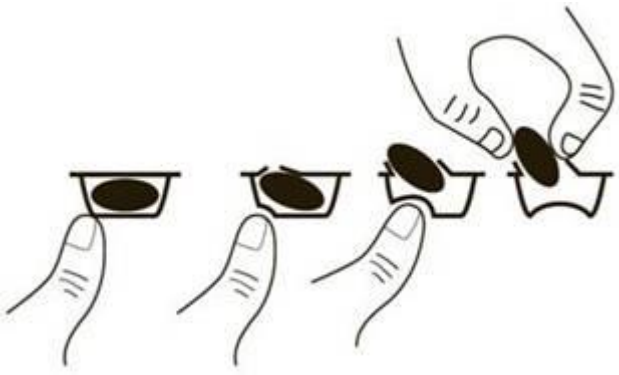
After completing your Thalidomide Celgene® treatment, it is important that:

- You return any unused Thalidomide Celgene® capsules to your pharmacist
- You do not donate blood for 1 week.

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.



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

- 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

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 minimize 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 minimize 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.

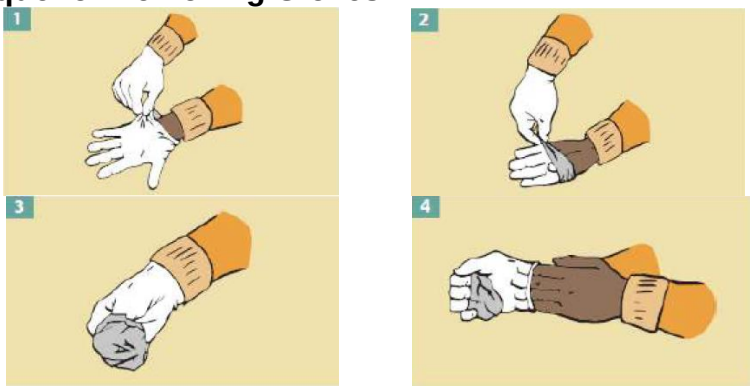
- Please report to the prescribing physician and/or pharmacist immediately.

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.

Personal Notes

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

Check List

Please use this check list to confirm that you have understood all of the important information regarding your Thalidomide Celgene® treatment.

Yes, I have received and understood all the information on the risks of birth defects associated with taking Thalidomide Celgene®.	
Yes, I have received and understood all the information on the risks of other side effects associated with taking Thalidomide Celgene®.	
Yes, I understand that I need to sign the *Treatment Initiation Form* before starting treatment.	

Further Information

Further information regarding your Thalidomide Celgene® 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**