Thalidomide Celgene®

Pregnancy Prevention Programme

Information for Patients Taking
Thalidomide Celgene®

UK
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 and arteries and, 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®.

This booklet will not give you information about multiple myeloma, you should ask your Doctor if you have any questions regarding myeloma.

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.

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 ‘immunomodulatory’ 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® is now approved in the European Union for the treatment of multiple myeloma 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, approximately 5,000 survive today.

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, including how to prevent pregnancy
- Understand what to expect during your initial and follow-up consultations with your doctor.
- 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.

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.
Thalidomide Celgene® and Birth Defects

All medicines can cause unwanted effects or ‘side effects’. An extremely 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.

Advice for Women of Childbearing Potential

During treatment if you miss or think you have missed a period, or you have any unusual menstrual bleeding, or suspect you are pregnant or if you have heterosexual intercourse without using an effective method of contraception, you must **stop treatment** and **tell your doctor straight away**.

Advice for Males

Thalidomide is present in semen. This means that men taking Thalidomide Celgene® must use pregnancy prevention measures every time they have intercourse with a woman who is able to become pregnant.

If you have a female partner who is able to become pregnant, then during your treatment if they miss or think they have missed a period, or have any unusual menstrual bleeding, or suspect they may be pregnant, you must **tell your doctor straight away**. Your partner must also **tell her doctor straight away**.

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. You may also report any side effect to the UK Medicines and Healthcare Products Regulatory Agency via their “Yellow Card” scheme, by using their web site at www.mhra.gov.uk/yellowcard.

**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 or inside of your mouth. You may have a high temperature (fever) at the same time.

**Tell your 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 or “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.
Before Starting Your Treatment

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 agree not to become pregnant
- You understand the other important safety messages.

Your doctor will keep this form with your medical records.

Childbearing Potential Assessment

Female patients will be assessed by their doctors for childbearing potential, and unless you fall into one of the following categories you must follow the pregnancy prevention advice presented in the next section:

- 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 still a chance you could become pregnant)
- 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/adolescent who has not reached menstruation (started having periods), and cannot become pregnant.

Pregnancy Prevention Advice for Women of Childbearing Potential

Prior to starting treatment your doctor will talk to you about the pregnancy prevention measures that you must follow. If you could become pregnant you must use one effective method of pregnancy prevention:

- At least 4 weeks before starting Thalidomide Celgene® treatment
- During treatment, even if there are breaks in your treatment
- Until at least 4 weeks after stopping treatment.

Effective female pregnancy prevention methods are:

- Hormonal pregnancy prevention measures implanted under the skin
- Pregnancy prevention coil placed in the uterus
- Long acting pregnancy prevention hormonal injection
- Female sterilisation
- Progestogen-only pill that prevents release of an egg from the ovaries
- Male partner’s vasectomy, which must be confirmed by two negative semen tests
- Abstinence from heterosexual intercourse.

It is important that you do not change pregnancy prevention methods without talking to your doctor first.

If you are pregnant or trying to become pregnant, you must not take Thalidomide Celgene®. If you are able to have children your doctor will perform regular pregnancy tests to confirm that you are not pregnant before taking Thalidomide Celgene®.

- You must have been using an effective pregnancy prevention method for at least 4 weeks before Thalidomide Celgene® can be prescribed
- A pregnancy test will take place every 4 weeks
- Your doctor will perform the pregnancy test during the consultation when Thalidomide Celgene® is prescribed, or in the previous three days
- Additional pregnancy tests must be performed if you miss your period or have any unusual menstrual bleeding
- A pregnancy test will take place at least 4 weeks after stopping treatment.

It is important that you understand and follow the pregnancy prevention methods and pregnancy testing information described.

- Pregnancy tests must be performed every 4 weeks even if you think there is no chance you have become pregnant since your last test
- Pregnancy prevention methods must be followed 4 weeks before starting treatment, during treatment, and until at least 4 weeks after stopping treatment
- Talk to your doctor before changing any pregnancy prevention method
- If you have heterosexual intercourse without using an effective pregnancy prevention method, stop taking Thalidomide Celgene® and talk to your doctor straight away
- If you think you are pregnant, stop taking Thalidomide Celgene® and contact your doctor straight away.
Pregnancy Prevention Advice for Males

Prior to starting treatment your doctor will talk to you about the pregnancy prevention measures that you must follow if you have a female partner who is pregnant or who is able to get pregnant, as you must protect her against any exposure to Thalidomide Celgene®. This means that if your partner is pregnant, or is not using an effective form of pregnancy prevention, you must use condoms every time you have intercourse:

- During treatment, even if there are breaks in your treatment
- Until 1 week after stopping treatment.

If you have a female partner who is pregnant or who is able to get pregnant, you must both tell your doctors immediately if:

- You have intercourse without using pregnancy prevention measures
- You think your male or female pregnancy prevention measure has failed
- Your partner misses a period or has any unusual menstrual bleeding during your treatment.

Safety Measures During Treatment

There are additional measures you must understand while 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, and men must also not donate semen, while you are being treated with Thalidomide Celgene®, and for one week after stopping treatment

- If you are a woman who is breastfeeding, your doctor will advise you either to stop breastfeeding or to stop taking Thalidomide Celgene® while breastfeeding. It is not known if Thalidomide Celgene® is passed into human breast milk.

Receiving Your Prescription

When your doctor writes your prescription they will also provide you with a ‘Prescription Authorisation Form’ 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 this documentation prior to dispensing your Thalidomide Celgene®.

For women of childbearing potential your doctor will write a prescription for no more than 4 weeks supply. Ideally, you should have the prescription dispensed within 7 days of the prescription date.

For women of non-childbearing potential and male patients your doctor will write a prescription for no more than 12 weeks supply.

You will need to see your doctor each time you need a repeat prescription.
End of Treatment Requirements

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.

Additional advice for women of childbearing potential:

- Continue using your effective pregnancy prevention method for at least a further 4 weeks
- Your doctor will perform a final pregnancy test after at least 4 weeks.

Additional advice for male patients:

- If you have been using an effective pregnancy prevention method, you must continue doing so for 1 week
- If your female partner has been using an effective pregnancy prevention method, she must continue doing so for at least 4 weeks
- Do not donate blood or semen for 1 week.

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.
- Yes, I have received and understood the pregnancy prevention advice.

Personal Notes

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