Thalidomide Celgene®
Pregnancy Prevention Programme

Male Treatment Initiation Form

UK

Introduction

This Treatment Initiation Form must be completed for each male patient prior to the initiation of their Thalidomide Celgene® treatment. Retain a copy of this form with their medical records, and provide a photocopy to the patient.

The aim of the Treatment Initiation Form is to protect patients and any possible unborn children by ensuring that patients are fully informed of and understand the risk of teratogenicity and other adverse effects associated with the use of thalidomide. It is not a contract and does not absolve anybody from his/her responsibilities with regard to the safe use of the product and prevention of foetal exposure.

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.

Patient Details

Patient First Name:																							
Patient Last Name:																							

Date of Birth:	*DD*	*MM*	*YYYY*	Counselling Date:	*DD*	*MM*	*YYYY*

Pregnancy Prevention

The patient confirms that:	
They will use a condom during intercourse with a woman of childbearing potential	*Tick*
Their female partner is using an effective method of pregnancy prevention	*Tick*
Their female partner is of non-childbearing potential	*Tick*
They are committed to complete and absolute abstinence	*Tick*

Prescriber Confirmation

I have fully explained to the patient named above the nature, purpose and risks of the treatment associated with Thalidomide Celgene® , especially the risks to women of childbearing potential.

Prescriber First Name :				
Prescriber Last Name:				
Prescriber Signature:		Date:	DD MM YYYY	

Patient: please read thoroughly and initial the adjacent box if you agree with the statement

I understand that severe birth defects can occur following exposure to Thalidomide Celgene® . I have been warned by my doctor that any unborn baby has a high risk of birth defects and could even die if a woman becomes pregnant following exposure to Thalidomide Celgene® or is exposed to Thalidomide Celgene® whilst pregnant.	Patient initials
I have been told by my doctor that I must NEVER have unprotected sexual contact with women who are pregnant, or may become pregnant, while I am taking Thalidomide Celgene® and for 1 week after stopping treatment.	Patient initials
I know that I must inform my doctor if I think that my sexual partner may be pregnant.	Patient initials
I understand that Thalidomide Celgene® will be prescribed ONLY for me. I must not share it with ANYONE.	Patient initials
I have read the Thalidomide Celgene® Patient Booklet and understand the contents, including the information about other possible health problems (side effects) from thalidomide.	Patient initials
I understand that I cannot donate blood or semen while taking Thalidomide Celgene® , or for 1 week after stopping treatment.	Patient initials
I understand that I must return any unused Thalidomide Celgene® to my pharmacy at the end of my treatment.	Patient initials

Patient Confirmation

I confirm that I understand and will comply with the requirements of the Thalidomide Celgene® Pregnancy Prevention Programme, and I agree that my doctor can initiate my treatment with Thalidomide Celgene® .

Patient Signature:		Date:	DD MM YYYY	

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