Thalidomide
Pregnancy Prevention Programme

Women of Non-Childbearing Potential
Treatment Initiation Form
UK

Introduction

This Treatment Initiation Form must be completed for each woman of non-childbearing potential prior to the initiation of their Thalidomide treatment. The form should be retained with their medical records, and a copy provided to the patient.

It is mandatory that women of non-childbearing potential receive counselling and education to be made aware of the risks of thalidomide. The aim of the Treatment Initiation Form is to protect patients and any possible foetuses 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

Thalidomide is a powerful human teratogen, inducing a high frequency of severe and life-threatening birth defects. Thalidomide must never be used by women who are pregnant, or by women who could become pregnant unless all the conditions of the Pregnancy Prevention Programme are met. The conditions of the Pregnancy Prevention Programme must be fulfilled for all male and female patients. If thalidomide is taken during pregnancy it can cause **severe life-threatening 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*

Prescriber Confirmation

I have fully explained to the patient named above the nature, purpose and risks of the treatment associated with Thalidomide, especially the risks to women of childbearing potential. I will comply with my obligations and responsibilities as the prescribing physician of Thalidomide.

I confirm I have informed the patient (data subject) that their personal data will be communicated to Accord-UK Ltd for the purpose of complying with a legal obligation (pharmacovigilance) in line with article 13 of the General (EU) 2016/679 Data Protection Regulation.

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 with the use of thalidomide. I have been warned by my prescriber that any unborn baby has a high risk of birth defects and could even die if a woman is pregnant or becomes pregnant while taking thalidomide.	*Patient initials*
I understand that thalidomide will be prescribed ONLY for me. I must not share it with ANYONE.	*Patient initials*
I know that I cannot donate blood while taking thalidomide (including dose interruptions) and for at least 7 days after stopping treatment.	*Patient initials*
I have read the thalidomide Patient brochure and understand the contents, including the information about other possible important health problems (side effects) from thalidomide.	*Patient initials*
I understand that I must return any unused thalidomide capsules 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 Pregnancy Prevention Programme, and I agree that my doctor can initiate my treatment with Thalidomide.

Patient signature		Date:	*DD*	*MM*	*YYYY*

The personal data provided by you will be processed by Accord-UK Ltd for the purpose of complying with a legal obligation (pharmacovigilance). For further information on how to exercise your rights and how we process your data, visit our privacy policy available on our website www.accord-healthcare.com

Statement of the interpreter (where appropriate)

I have interpreted the information above to the patient/parent to the best of my ability and in a way in which I believe she/he/they can understand. She/he/they agree to follow the necessary precautions to prevent an unborn child being exposed to thalidomide.

Signed:		Name: (print)		Date:	*DD*	*MM*	*YYYY*

Accord-UK Ltd, Whiddon Valley, Barnstaple, Devon, EX32 8NS, UK.
Phone: +44 (0)7917920374
Fax: 01271 346106
Website: www.accord-healthcare.co.uk

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