Thalidomide
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 treatment. The form should be retained with their medical records, and a copy provided to the patient.
It is mandatory that males receive counselling and education to be made aware of the risk 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*

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 contraception	*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, especially the risks to women of childbearing potential. I will comply with all 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*

Men Treatment Initiation Form

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 passes into human semen. If my partner is pregnant or able to become pregnant, and she doesn't use effective contraception, I must use condoms throughout the duration of my treatment, during dose interruptions and for at least 7 days after I stop thalidomide even if I have had a vasectomy.	Patient initials
I know that I must inform my prescriber immediately if I think that my partner may be pregnant while I am taking thalidomide or within 7 days after I have stopped taking thalidomide and my partner should be referred to a physician specialised or experienced in teratology for evaluation and advice.	Patient initials
I understand that Thalidomide will be prescribed ONLY for me. I must not share it with ANYONE.	Patient initials
I have read the Thalidomide Patient brochure and understand the contents, including the information about other possible health problems (side effects) from thalidomide.	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 understand that I must return any unused Thalidomide to my pharmacy at the end of my treatment.	Patient initials
I have been informed about which are effective contraceptive methods that my female partner can use.	Patient initials
I know that I cannot donate semen or sperm while taking thalidomide, during dose interruptions and for at least 7 days after stopping treatment	Patient initials

Patient Confirmation

I confirm that I understand and will comply with the requirements of the Thalidomide Pregnancy Prevention Programme. I agree that my prescriber 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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