Thalidomide
Pregnancy Prevention Programme

Woman of Childbearing Potential
Treatment Initiation Form

UK

Introduction

This Treatment Initiation Form must be completed for each woman of childbearing potential prior to the initiation of their thalidomide treatment. The form should be retained with their medical records and provide a photocopy to the patient.

It is mandatory that women of childbearing potential receive counselling and education to be made aware of the risks of thalidomide. Thalidomide is contraindicated in women of childbearing potential unless all terms of counselling are met.

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*

Contraceptive Referral

Contraceptive referral required	*YES*	*NO*

Contraceptive referral made	*DD*	*MM*	*YYYY*
Contraceptive consultation conducted on	*DD*	*MM*	*YYYY*

Pregnancy Prevention

The patient has been established on one of the following for at least 4 weeks	
Implant	*Tick*
Levonorgestrel-releasing intrauterine system (IUS)	*Tick*
Medroxyprogesterone acetate depot	*Tick*
Tubal sterilisation	*Tick*
Sexual intercourse with a vasectomised male partner only; vasectomy must be confirmed by two negative semen analyses	*Tick*
Ovulation inhibitory progesterone-only pills (i.e. desogestrel)	*Tick*
Committed to complete and absolute abstinence	*Tick*

Pregnancy Test

Date of last negative pregnancy test	*DD*	*MM*	*YYYY*

Thalidomide treatment cannot start until the patient has been established on an effective method of contraception for at least 4 weeks, or commits to complete and continuous abstinence, and obtains a negative pregnancy test.

Woman of Childbearing Potential Treatment Initiation Form

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 prescriber 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 I must not take thalidomide if I am pregnant or plan to become pregnant.	Patient initials
I understand that I must use one effective method of contraception without interruption, for at least 4 weeks before starting treatment, throughout the entire duration of treatment and even in the case of dose interruptions, and for at least 4 weeks after the end of treatment or commit to absolute and continuous sexual abstinence confirmed on a monthly basis. An effective method of contraception must be initiated by an appropriately trained healthcare professional.	Patient initials
I understand that if I need to change or stop my method of contraception, I will discuss this first with the physician prescribing my contraception method and the physician prescribing my thalidomide.	Patient initials
I understand that before starting the Thalidomide treatment I must have a medically supervised pregnancy test. I will then have a pregnancy test every 4 weeks during treatment, and a test at least 4 weeks after the end of treatment.	Patient initials
I understand that I must immediately stop taking thalidomide and inform my treating prescriber immediately upon suspicion of pregnancy while taking this drug (including dose interruptions); or if I miss my menstrual period or experience any unusual menstrual bleeding; or think **FOR ANY REASON** that I may be pregnant.	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 understand that even if I have amenorrhoea I must comply with advice on contraception.	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

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MHRA approval date - 25/07/2022
BBBB4776