Thalidomide Pregnancy Prevention Programme
Women of Non-ChildBearing Potential (WNCBP) Risk Awareness Form

RISK AWARENESS FORM FOR COUNSELLING THE PATIENT TO ENSURE THE PATIENT IS FULLY INFORMED ABOUT THE SAFE USE OF THALIDOMIDE

This Risk Awareness Form is to assist you with counselling a patient before they commence thalidomide treatment in order to ensure it is used safely and correctly. It must be completed for each woman of non-childbearing potential prior to the initiation of their thalidomide treatment. This form must be completed by a physician experienced in managing immunomodulatory drugs.

The purpose of the Risk Awareness 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 drug reactions associated with the use of thalidomide. It is mandatory that woman of non-childbearing potential receive counselling and education to be made aware of the risks of thalidomide.

The form should be retained with their medical records, and a photocopy provided to the patient. It is not a contract and does not absolve anybody from his/her responsibilities regarding 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

Did you inform your patient

1) To not share the medicinal product with any other person.	Tick
2) That they should not donate blood during treatment (including during dose interruptions) and for at least 7 days following discontinuation of thalidomide.	Tick
3) That they should return the unused capsules to the pharmacist at the end of treatment	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.

Prescriber First Name:

Prescriber Last Name:

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Pathfinder
Risk Management Platform

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 have read the thalidomide Patient Brochure and understand the contents, including the information about other possible important health problems (side effects) associated with the use of 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 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 prescriber can initiate my treatment with thalidomide.

I understand that in order to receive thalidomide as part of the medical care and treatment that I am receiving, my personal data will be collected and processed by the NHS and the relevant Marketing Authorisation Holder (i.e. the supplier of thalidomide) and their processors, HealthBeacon plc and Pharmacare Group Ltd. I further understand that my personal data will be processed and retained in accordance with the relevant party's privacy policy, which can be found on their website.

Patient Signature:	

Date:	DD	MM	YYYY

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.

Interpreter Signature:		**Name:** (print)	

Date:	DD	MM	YYYY

For further information, please refer to the Summary of Product Characteristics (SmPC) for the respective medicinal product from the relevant Marketing Authorisation Holders or refer to the MHRA www.mhra.gov.uk

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