Thalidomide BMS® (thalidomide) Pregnancy Prevention Programme

Woman of Non-Childbearing Potential Risk Awareness Form

IRELAND

Version 7.0

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

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.

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's First Name:																							
Patient's Last Name:																							

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

Did you inform your patient:	Woman of Non-Childbearing Potential
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*
4) Of the hazards and necessary precautions associated with use of the thalidomide.	*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 prescriber of thalidomide.

Prescriber's First Name :																							
Prescriber's 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 have read the thalidomide Patient Guide and understand the contents, including the information about other possible important 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 capsules to my pharmacy at the end of my treatment.	Patient initials
I understand that my prescriber will provide me with a 'Prescription Authorisation Form' with each thalidomide prescription, and that I must provide this to my pharmacy.	Patient initials
I understand that the 'Prescription Authorisation Form' contains non identifiable information about me, which will ensure thalidomide is dispensed safely. The information may also be used by the Marketing Authorisation Holder, the distributor of the product and the Health Products Regulatory Authority (HPRA) to evaluate the safe use of thalidomide.	Patient initials

Patient Confirmation

I confirm that I understand and will comply with the requirements of the Thalidomide BMS® Pregnancy Prevention Programme. I agree that my prescriber can initiate my treatment with thalidomide.

This form will be kept by your doctor. Your personal data (collected on the Prescription Authorisation Form (PAF) or Order Form) will be processed by Bristol-Myers Squibb Pharma EEIG ("BMS"), as the marketing authorisation holder of Thalidomide BMS® and the distributor for the purpose(s) of managing the Pregnancy Prevention Programme.

Your data will be kept for as long as necessary, for the purposes of compliance with the Risk Management Plan legal obligations and for storage purposes.

Should you have any queries in relation to the use of your personal data please contact your doctor or BMS at: eudpo@bms.com. If you are unhappy about how your personal data is being processed, you have the right to lodge a complaint with the supervisory authority.

Patient Signature:		Date:	DD	MM	YYYY

Statement of the interpreter (where appropriate)

I have interpreted the information above to the patient/parent/carer 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

Bristol Myers Squibb™

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