

Thalidomide BMS[®] (thalidomide) Pregnancy Prevention Programme

Woman of Non-Childbearing Potential Risk Awareness Form

IRELAND

Version 7.0

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
---------	--	---------------	--	-------	----	----	------

