Thalidomide
Pregnancy Prevention Programme

Women of Non-Childbearing Potential
Risk Awareness Form

Healthcare professionals are asked to report any suspected adverse reactions using the Yellow Card Scheme via https://yellowcard.mhra.gov.uk
or by searching for MHRA Yellow Card in the Google Play or Apple App Store.

Adverse reactions should also be reported to Accord Medical Information on 01271 385257
or medinfo@accord-healthcare.com

Woman of Non-Childbearing Potential 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 with expertise 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 effects 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 copy provided to the patient. 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

Did you inform your patient

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

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 prescribing physician of thalidomide.

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 have read the Thalidomide Patient Brochure and understand the contents, including the information about other possible important health problems (side effects) from 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 doctor can initiate my treatment with Thalidomide.

This form will be kept by your doctor. Your personal data (collected on the Prescription Authorisation Form (PAF)) will be processed by Accord-UK Ltd as the Marketing Authorisation Holder of Thalidomide 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 Accord. 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 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 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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