Thalidomide
Pregnancy Prevention Programme

Male 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

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 male 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.

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

	MALE
1 Of the need to avoid foetal exposure	
2 To not share the medicinal product with any other person	
3 That they should not donate blood during treatment (including during dose interruptions) and for at least 7 days following discontinuation of thalidomide	
4 That they should return the unused capsules to the pharmacist at the end of treatment	
5 That thalidomide is found in semen, so there is a need to use condoms if the sexual partner is pregnant or is a woman of childbearing potential not on effective contraception (even if the man has had a vasectomy) throughout treatment duration, during dose interruption and for at least 7 days after cessation of treatment.	
6 That if his partner becomes pregnant, he should inform his treating doctor immediately, his partner should be referred to a physician specialised or experienced in teratology for evaluation and advice and always use a condom	
7 That he should not donate semen during treatment (including during dose interruptions) and for at least 7 days following discontinuation of thalidomide	

Pregnancy Prevention

The patient confirms that:

They will use a condom during intercourse with a woman of childbearing potential	
Their female partner is using an effective method of contraception	
Their female partner is of non-childbearing potential	
They are committed to complete and absolute abstinence	

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:																							

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 passes into human semen. If my partner is pregnant or able to become pregnant, and she doesn't use effective contraception, I must use condoms throughout the duration of my treatment, during dose interruptions and for at least 7 days after I stop thalidomide even if I have had a vasectomy.	Patient initials
I know that I must inform my prescriber immediately if I think that my partner may be pregnant while I am taking thalidomide or within 7 days after I have stopped taking thalidomide and my partner should be referred to a physician specialised or experienced in teratology for evaluation and advice.	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 have been informed about which are effective contraceptive methods that my female partner can use.	Patient initials
I know that I cannot donate semen or sperm while taking thalidomide, during dose interruptions and for at least 7 days after stopping treatment	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.

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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MHRA approval date - 24/04/2024
BBBB9298