Thalidomide
Pregnancy Prevention Programme

Woman of 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 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 female patient of 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 women of childbearing potential receive counselling and education to be made aware of the risks of thalidomide. Thalidomide is contraindicated in women of childbearing potential unless all terms of counselling are met.

This 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

		WCBP
1	Of the expected teratogenic risk to the unborn child and need to avoid foetal exposure	
2	That if she is pregnant or plans to be, she must not take thalidomide	
3	Of the need to avoid thalidomide during pregnancy and to apply effective contraceptive measures without interruption, at least 4 weeks before starting treatment, throughout the entire duration of treatment, and at least 4 weeks after the end of treatment	
4	That if she needs to change or stop using her method of contraception she should inform a) the physician prescribing her contraception that she is taking thalidomide b) the physician prescribing thalidomide that she has stopped or changed her method of contraception	
5	Of the need for pregnancy tests (i.e. before treatment) at least every 4 weeks during treatment and after treatment	
6	Of the need to stop thalidomide immediately upon suspicion of pregnancy	
7	Of the need to contact their doctor immediately on suspicion of pregnancy	
8	To not share the medicinal product with any other person	
9	That they should not donate blood during treatment (including during dose interruptions) and for at least 7 days following discontinuation of thalidomide	
10	That they should return the unused capsules to the pharmacist at the end of treatment	

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Can you confirm your patient

1	Was referred to a contraceptive consultant, if required?	Y/N
2	Is capable of complying with contraceptive measures?	Y/N
3	Agreed to undergo pregnancy testing at least in 4 weekly intervals unless confirmed tubal sterilisation?	Y/N
4	Has a negative pregnancy test before staring treatment even if absolute and continued abstinence?	Y/N

Contraceptive Referral (if answered yes to question 1 above)

Contraceptive referral made	DD	MM	YYYY
Contraceptive consultation conducted on	DD	MM	YYYY

Pregnancy Prevention

The patient has been established on one of the following for at least 4 weeks	
Implant	
Levonorgestrel-releasing intrauterine system (IUS)	
Medroxyprogesterone acetate depot	
Tubal sterilisation	
Sexual intercourse with a vasectomised male partner only; vasectomy must be confirmed by two negative semen analyses	
Ovulation inhibitory progesterone-only pills (i.e. desogestrel)	
Committed to complete and absolute abstinence	

Pregnancy Test

Date of last negative pregnancy test	DD	MM	YYYY

TREATMENT FOR A WOMAN OF CHILDBEARING POTENTIAL CANNOT START UNTIL THE PATIENT IS ESTABLISHED ON AT LEAST ONE EFFECTIVE METHOD OF CONTRACEPTION FOR AT LEAST 4 WEEKS PRIOR TO INITIATION OF THERAPY OR COMMITS TO COMPLETE AND CONTINUOUS ABSTINENCE, AND PREGNANCY TEST IS NEGATIVE.

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 prescriber of Thalidomide.

Prescriber First Name:			
Prescriber Last Name:			
Prescriber signature:		Date:	DD MM YYYY

Woman of Childbearing Potential Risk Awareness Form

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 I must not take thalidomide if I am pregnant or plan to become pregnant.	Patient initials
I understand that I must use one effective method of contraception without interruption, for at least 4 weeks before starting treatment, throughout the entire duration of treatment and even in the case of dose interruptions, and for at least 4 weeks after the end of treatment or commit to absolute and continuous sexual abstinence confirmed on a monthly basis. An effective method of contraception must be initiated by an appropriately trained healthcare professional.	Patient initials
I understand that if I need to change or stop my method of contraception I will discuss this first with • the physician prescribing my contraception method • the physician prescribing my thalidomide.	Patient initials
I understand that before starting the thalidomide treatment I must have a medically supervised pregnancy test. I will then have a pregnancy test every 4 weeks during treatment, and a test at least 4 weeks after the end of treatment.	Patient initials
I understand that I must immediately stop taking thalidomide and inform my treating prescriber immediately upon suspicion of pregnancy while taking this drug (including dose interruptions); or if I miss my menstrual period or experience any unusual menstrual bleeding; or think **FOR ANY REASON** that I may be pregnant.	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 understand that even if I have amenorrhoea I must comply with advice on contraception.	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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