

Informed consent form for women of childbearing potential treated with Myrin® 50 mg and 100 mg tablets (Thalidomide)

Introduction

This form must be completed and signed by each female patient prior to the initiation of their therapy with Myrin® 50 mg and 100 mg tablets (Thalidomide).

The aim of this treatment initiation form is to ensure that patients are fully informed and understand the risk of malformations and even death for the unborn baby associated with the intake of thalidomide.

WARNING: Severe-life threatening birth defects! If Myrin® (Thalidomide) is taken during pregnancy it can cause severe birth defects or death to an unborn baby.

Patient declaration

I, the undersigned, Ms. _____ born the ___/___/____ confirm that:

I will use an effective method of contraception: - for 4 weeks before starting treatment - during treatment - until 12 weeks after stopping treatment	<input type="checkbox"/>
I was informed by my physician about the method of contraception that it will be used	<input type="checkbox"/>
I am committed to absolute abstinence	<input type="checkbox"/>
I was informed by my physician about the risks of the treatment with thalidomide and I agree with the following statements:	<input type="checkbox"/>
<ul style="list-style-type: none"> • I understand that severe birth defects can occur after exposure to Myrin® (Thalidomide). 	<input type="checkbox"/>
<ul style="list-style-type: none"> • I have been warned by my doctor that any unborn baby has a high risk of birth defects and could also die if I am pregnant or become pregnant while taking Myrin® (Thalidomide) 	<input type="checkbox"/>
<ul style="list-style-type: none"> • I understand that I must use an effective method of pregnancy prevention without interruption for at least 4 weeks before starting treatment and for at least 12 weeks after the end of treatment 	<input type="checkbox"/>
<ul style="list-style-type: none"> • I understand that if I need or want to change my method of pregnancy prevention, I need to discuss it first with my doctor 	<input type="checkbox"/>
<ul style="list-style-type: none"> • I understand that before starting treatment with Myrin® (thalidomide) I will have a pregnancy test before treatment, every 4 weeks during treatment and 4 weeks after stopping treatment. 	<input type="checkbox"/>
<ul style="list-style-type: none"> • I must inform my doctor if I think that I may be pregnant or I miss my menstrual period or experience unusual menstruation bleeding 	<input type="checkbox"/>
<ul style="list-style-type: none"> • I understand that Myrin® (Thalidomide) was prescribed only for me, I will not share it with anyone else 	<input type="checkbox"/>
<ul style="list-style-type: none"> • I will not drink any alcohol while taking Myrin® 	<input type="checkbox"/>
<ul style="list-style-type: none"> • I have read the Myrin® (Thalidomide) patient information and understood its content 	<input type="checkbox"/>
<ul style="list-style-type: none"> • I understand that I cannot donate blood while taking Myrin® (Thalidomide) up to 12 weeks after stopping therapy 	<input type="checkbox"/>
<ul style="list-style-type: none"> • I understand that I have to return any unused Myrin® (Thalidomide) tablets to the pharmacy at the end of my treatment 	<input type="checkbox"/>

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Reporting of any other adverse events

Suspected Adverse Drug Reactions (side effects) and medication errors may be reported using the Malta Medicines Authority ADR reporting form, which is available online at

<http://www.medicinesauthority.gov.mt/adrportal> and sent by post or email to;

P: Pharmacovigilance Section at Post-Licensing Directorate, Medicines Authority, Sir Temi Zammit Buildings, Malta Life Sciences Park, San Gwann. SGN 3000.

E: postlicensing.medicinesauthority@gov.mt.

Healthcare Professionals may also report any adverse events associated with the use of Myrin to Cherubino Ltd on 21343270 or pharmacovigilance@cherubino.com.mt

Patient Signature

Patient name (first and second name)	Place and Date:
Patient Signature	

Prescriber signature

Prescriber name (first and second name)	Place and Date:
Prescriber Signature	