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**	☐
I was informed by my physician about the method of contraception that is more adapt to me	☐
I am committed to absolute abstinence	☐
I was informed by my physician about the risks of the treatment with thalidomide and I agree with the following statements:	☐
• I understand that severe birth defects can occur after exposure to Myrin® (Thalidomide).	☐
• 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)	☐
• 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	☐
• I understand that if I need or want to change my method of pregnancy prevention, I need to discuss it first with my doctor	☐
• 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.	☐
• I must inform my doctor if I think that I may be pregnant or I miss my menstrual period or experience unusual menstruation bleeding	☐
• I understand that Myrin® (Thalidomide) was prescribed only for me, I will not share it with anyone else	☐
• I will not drink any alcohol while taking Myrin®	☐
• I have read the Myrin® (Thalidomide) patient information and understood its content	☐
• I understand that I cannot donate blood while taking Myrin® (Thalidomide) up to 12 weeks after stopping therapy	☐
• I understand that I have to return any unused Myrin® (Thalidomide) tablets to the pharmacy at the end of my treatment	☐

Reporting of any other adverse events

In the instance of any adverse event suspected to be related to the treatment with Myrin® (Thalidomide) you must also report it to the Malta Medicines Authority by post or e-mail: ADR reporting/ Sir Temi Zammit Building, Malta Life Sciences Park, San Gwann or on www.medicinesauthority.gov.mt/adrportal using the adverse drug reaction form of the Medicines Authority www.maltamedicinesauthority gov.mt

OR report it to Cherubino Ltd on 21343270 or elaine@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	