Informed consent form for men treated with Myrin® 50 mg and 100 mg tablets (Thalidomide)

Introduction

This form must be completed and signed by each male 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, Mr._____ born the___/___/_____ confirm that:

I will use a condom during intercourse with a woman of childbearing potential	☐
My female partner is using an effective method of pregnancy prevention	☐
My female partner is of non-childbearing potential	☐
Or 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 a woman is pregnant or become pregnant while taking Myrin® (Thalidomide)	☐
• I was talked by my doctor to never have unprotected sexual contact with women who are pregnant or may become pregnant while I am taking Myrin® (Thalidomide) and for 1 week after I stopped	☐
• I must inform my doctor if I think that my partner may be pregnant	☐
• 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 semen and blood while taking Myrin® (thalidomide) up to 12 weeks after stopping therapy	☐
• I understand that I have to return any unused Myrin® tablets (thalidomide) to the pharmacy at the end of my treatment	☐

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	