Dispensation guide for Myrin® 50 mg and 100 mg tablets (Thalidomide) and receipt form for pharmacists

Introduction

I, the undersigned, hereby certify that I am aware that Myrin® 50 mg and 100 mg tablets (Thalidomide) is approved for the treatment of patients with multiple myeloma.

The precautions outlined in this document must be followed also in case Myrin® is used for another indication than the approved one or in another treatment setting than the authorised one.

WARNING Myrin Teratogenic effects:

Thalidomide is a powerful human teratogen, inducing a high frequency of severe and life-threatening birth defects. Thalidomide must not be used by women who are pregnant or by women who could become pregnant unless the requirements and conditions outlined in the Certificate of Responsibility, which is part of the program of prevention and minimization of the risks, are met. Women who could become pregnant must take all of the necessary steps to ensure that they are not pregnant before treatment and that they do not become pregnant during the treatment and for at least 12 weeks after treatment.

I, the undersigned, hereby certify that I have received a prescription of Myrin® (Thalidomide) from the patient including the following documents:

a. **Myrin® (thalidomide) prescription/order form**
b. **Pharmacist dispensation guide of Myrin® (Thalidomide) and receipt form**

I, the undersigned, hereby understand and accept that Myrin® may be prescribed only if the following conditions are fulfilled:

1. I have received a prescription for Myrin® 50 mg and 100 mg tablets (Thalidomide) in which the name of the prescriber and the patient are clearly specified.
2. The patient or her/his legal representative, being of sound mind, has given written informed consent to be treated with thalidomide by initialling and signing the Informed consent, a copy of which was attached to the prescription, and of which I made a copy for myself.
3. I asked and was confirmed by the patient that the rationale for the treatment has been explained to the patient, any questions have been answered.
4. Thalidomide is a powerful human teratogen; I have read carefully the information kit and the Summary of Product Characteristics on Myrin concerning teratogenicity.
5. I asked and was confirmed by the patient that he was informed by the physician about the risk of damage to babies for pregnant women and the patient is informed of the need to use a method of contraception, without interruption, 4 weeks before starting therapy, during therapy and for 12 weeks after thalidomide therapy, having a negative pregnancy test before starting therapy and having pregnancy tests every 4 weeks including 4 weeks after the end of therapy.

How to order and dispense Myrin® (Thalidomide), Dispenser obligations

As a pharmacist you play an important role in ensuring that Myrin® (thalidomide) is used safely and correctly. You must ensure that the required documents for dispensation are available to you before ordering Myrin® (thalidomide).

When you order Myrin® (thalidomide) you must provide the distributor with:

- the completed prescription form indicating the doctor
- the signed Pharmacist dispensation guide of Myrin® (Thalidomide) and receipt form

Dispensation guide for Myrin® 50 mg and 100 mg tablets (Thalidomide) and receipt form for pharmacists

Without these two documents the distributor cannot deliver Myrin® (Thalidomide) to you. Myrin® (thalidomide) will only be supplied to pharmacies, who order Myrin® (Thalidomide) together with this information

Dispensing

You must dispense Myrin® (thalidomide) in accordance with the measures described in this information.

Dispensing of Myrin® (Thalidomide) should occur within a maximum of 7 days of the prescription date

Please ensure that you dispense Myrin® (Thalidomide) packages intact; tablets must not be removed from blisters and packaged into bottles

Please educate all pharmacists within your pharmacy about the dispensing procedures for Myrin® (Thalidomide)

Instruct patients to return any unused Myrin® to the pharmacy. Pharmacies must accept any unused Myrin® (Thalidomide) returned by patients for destruction, and follow Good Pharmacy Practice guidelines for destruction of dangerous medicines.

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

Please retain the prescription for a minimum of 2 years.

Pharmacist signature

Pharmacist name (first and second name)	Place and Date:
Stamp or address	
Pharmacist Signature	