Receipt form of the information Kit for Myrin® 50 mg and 100 mg tablets (Thalidomide) for prescribers

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 the information kit for Myrin consisting of:

a. **Prescription guide of Myrin® (Thalidomide) for prescribers**
b. **Prescriber receipt form (Annex 1)**
c. **Pharmacist dispensation guide of Myrin® (Thalidomide) and receipt form (Annex 2)**
d. **Informed consent form for women of childbearing potential (Annex 3)**
e. **Informed consent form for women of non-childbearing potential (Annex 4)**
f. **Informed consent form for men (Annex 5)**
g. **Current product information (Annex 6)**
h. **Form for reporting of pregnancy (Annex 7)**
i. **Form for reporting of pregnancy outcome (Annex 8)**
j. **Form for reporting of adverse events (Annex 9)**

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

1. I accept responsibility for the treatment of the patient and any consequences of the treatment.
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 appropriate informed consent prior to the initiation of treatment. The patient has given the initialised and signed Patient Information Sheet back to me and kept a copy for himself/herself.
3. 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 content of the information kit and the Summary of Product Characteristics on Myrin concerning teratogenicity. In particular, the risk of damage to babies for pregnant women has been explained 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.

Receipt form of the information Kit for Myrin® 50 mg and 100 mg tablets (Thalidomide) for prescribers

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

Prescriber signature

<table>
<tr><td>Prescriber name (first and second name)</td><td></td></tr>
<tr><td rowspan="2">Stamp or address</td><td></td></tr>
<tr><td rowspan="2">Place and Date:</td></tr>
<tr><td>Prescriber Signature</td></tr>
</table>