Revlimid®

Patient Card

Key Elements of Patient Card for Revlimid® (lenalidomide)

Patient Name or Initials Date of Birth or Year of Birth or Age Group

Physician name
Address,
Phone number

Physician to complete each section.

1. Indication (please specify in detail according to SmPC)

2. Status of Patient (tick one)

- Female of non childbearing potential* ☐

(*no Pregnancy Prevention Programme (PPP) monitoring required)

- Male ☐

- Woman of childbearing potential ** ☐

**Please also complete section 4

Amend locally to insert instruction to retain card in records or amend as per local implementation as agreed with Member State.

3. Counselling regarding the expected human teratogenicity of lenalidomide and the need to avoid pregnancy has been provided before first prescription

Physician's Signature

Date

4. For Woman of Childbearing potential*

Date of Visit	Patient is using one effective method of contraception (Yes/No)	Date of NEGATIVE pregnancy test (IF APPLICABLE)	Confirmed no risk of pregnancy (PLEASE TICK)	Date of lenalidomide prescription	Physician signature

*Women of childbearing potential must have a medically supervised negative pregnancy test prior to issuing a prescription (with a minimum sensitivity of 25 mIU/ml) once she has been established on contraception for 4 weeks, at 4 weekly intervals during therapy (this includes dose interruptions) and 4 weeks after the end of therapy (unless confirmed tubal sterilisation). This includes those women of childbearing potential who confirm absolute and continued abstinence. For further information, refer to the Summary of Product Characteristics.

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Explanatory note:

The elements of the Patient Card may be incorporated and/or split into an equivalent local Risk Minimisation tool such as a Special Order Form, Prescription Authorisation Form, Verification Form, Treatment Passport, etc, depending on the local implementation of the Pregnancy Prevention Programme (PPP) as agreed with the National Competent Authority (NCA) in each Member State.

Prior to placing the product on the market, the methods for monitoring indication, dose, patient demographics and compliance with the PPP will be discussed with each NCA.