Patient Card

Zelvina®
(Lenalidomide)

Approved by the Malta Medicines Authority
on the 02nd of February 2024.

Patient Card for Lenalidomide

Patient Initials: Date of Birth:

Physician Name:
Physician Address:
Physician Phone number:

Physician to complete each section:

1. **Indication:**

   Multiple Myeloma:

   ☐ ndMM (newly diagnosed multiple myeloma)

   ☐ After at least one prior therapy: Line of therapy……

   Other: ☐ Specify……

2. **Status of Patient (tick one)**

- Male ☐
- Woman of non-childbearing potential* ☐

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

- Woman of childbearing potential ** ☐

**Please also complete section 4.

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

Patient's signature
Date
Physician's signature
Date

Copy of Patient Card to be given to patient

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	Dispensed by	Dispensed date

***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 Product Information.**

REPORTING OF ADVERSE REACTIONS
Suspected adverse reactions and medication errors should be reported either to:

ADR Reporting, The Medicines Authority, Post-Licensing Directorate,
Sir Temi Zammit Buildings, Malta Life Sciences Park,
San Gwann SGN 3000, Malta
Website: www.medicinesauthority.gov.mt
e-mail: postlicensing.medicinesauthority@gov.mt

OR

Adalvo Limited
Malta Life Sciences Park,
Sir Temi Zammit,
Building 1, Level 4,
San Gwann Industrial Estate,
San Gwann, SGN 3000,
Malta
Email: pharmacovigilance@adalvo.com
Tel: +0040 727251514

Marketing Authorisation Holder
Adalvo Limited