IMNOVID® (POMALIDOMIDE)

PATIENT CARD OR EQUIVALENT TOOL

Medicines Authority Approval Date: *18 October 2023*

Key Elements of Patient Card for Imnovid® (pomalidomide)

Patient Name, or Initials or Patient unique code/identifier:

Date of Birth or Year of Birth or Age Group: ☐

DD/MM/YYYY

Physician name (PRINT):
Address (PRINT):
Phone number:

Physician to complete each section.

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

2. Status of Patient (tick one)

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

(*Please also complete section 3)

. Patient Card is to be kept in the Patient File.

3. For Women of Childbearing Potential[a]

Date of Current Visit	Patient is Using at Least One Effective Method of Contraception (Check one)	Pregnancy Test Date	Pregnancy Test Result (Check one)	Date of Pomalidomide Prescription	Physician Name (PRINT)	Physician Signature
	☐ Yes ☐ No[b] ☐ Unknown[b]		☐ Positive ☐ Negative ☐ Inconclusive ☐ Not done[c]			
	☐ Yes ☐ No[b] ☐ Unknown[b]		☐ Positive ☐ Negative ☐ Inconclusive ☐ Not done[c]			
	☐ Yes ☐ No[b] ☐ Unknown[b]		☐ Positive ☐ Negative ☐ Inconclusive ☐ Not done[c]			
	☐ Yes ☐ No[b] ☐ Unknown[b]		☐ Positive ☐ Negative ☐ Inconclusive ☐ Not done[c]			
	☐ Yes ☐ No[b] ☐ Unknown[b]		☐ Positive ☐ Negative ☐ Inconclusive ☐ Not done[c]			
	☐ Yes ☐ No[b] ☐ Unknown[b]		☐ Positive ☐ Negative ☐ Inconclusive ☐ Not done[c]			

Date of Current Visit	Patient is Using at Least One Effective Method of Contraception (Check one)	Pregnancy Test Date	Pregnancy Test Result (Check one)	Date of Pomalidomide Prescription	Physician Name (PRINT)	Physician Signature
	☐ Yes ☐ No[b] ☐ Unknown[b]		☐ Positive ☐ Negative ☐ Inconclusive ☐ Not done[c]			
	☐ Yes ☐ No[b] ☐ Unknown[b]		☐ Positive ☐ Negative ☐ Inconclusive ☐ Not done[c]			
	☐ Yes ☐ No[b] ☐ Unknown[b]		☐ Positive ☐ Negative ☐ Inconclusive ☐ Not done[c]			
	☐ Yes ☐ No[b] ☐ Unknown[b]		☐ Positive ☐ Negative ☐ Inconclusive ☐ Not done[c]			
	☐ Yes ☐ No[b] ☐ Unknown[b]		☐ Positive ☐ Negative ☐ Inconclusive ☐ Not done[c]			

[a] 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 at least 4 weeks, at least in 4-weekly intervals during therapy (this includes dose interruptions) and at least 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.

[b] May include "specify reason" for a response of No or Unknown, within the form itself or in eRMP system, as applicable. Alternatively, follow up directly with HCP to obtain the reason for the responses.

[c] May include "specify reason" for a response of Not done, within the form itself or in eRMP system, as applicable. Alternatively, follow up directly with HCP to obtain the reason for the response.

4. Counselling regarding the expected human teratogenicity of pomalidomide and the need to avoid pregnancy has been provided to the patient before first prescription

Print Name	Physician's Signature

Date

1 REPORTING OF ADVERSE REACTIONS

The safe use of pomalidomide is of paramount importance. As part of BMS's ongoing safety monitoring, the company wishes to learn of Adverse Reactions that have occurred during the use of pomalidomide. . Please contact AM Mangion Ltd immediately on Tel No 00356 23976333 and email pv@ammangion.com

Suspected Adverse Drug Reactions (side effects) or medication errors may be reported using the 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 Żammit Buildings, Malta Life Sciences Park, San Ġwann SĠN 3000
E: postlicensing.medicinesauthority@gov.mt

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