Imnovid® (pomalidomide)

Patient Card

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

(*Please also complete section 3)

Copy of Patient Card to be given to patient.

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)	Next Appointment Date	Date of pomalidomide prescription	Physician name (PRINT)	Physician signature
	☐ Yes ☐ No. Specify reason: ________________ ☐ Unknown. Specify reason: ________________		☐ Positive ☐ Negative ☐ Inconclusive ☐ Not done. Specify reason:				
	☐ Yes ☐ No. Specify reason: ________________ ☐ Unknown. Specify reason: ________________		☐ Positive ☐ Negative ☐ Inconclusive ☐ Not done. Specify reason:				
	☐ Yes ☐ No. Specify reason: ________________ ☐ Unknown. Specify reason: ________________		☐ Positive ☐ Negative ☐ Inconclusive ☐ Not done. Specify reason:				

Date of Current Visit	Patient is using at least one effective method of contraception (Check one)	Pregnancy Test Date	Pregnancy Test Result (Check one)	Next Appointment Date	Date of pomalidomide prescription	Physician name (PRINT)	Physician signature
	☐ Yes ☐ No. Specify reason: ____________________ ☐ Unknown. Specify reason: ____________________		☐ Positive ☐ Negative ☐ Inconclusive ☐ Not done. Specify reason:				
	☐ Yes ☐ No. Specify reason: ____________________ ☐ Unknown. Specify reason: ____________________		☐ Positive ☐ Negative ☐ Inconclusive ☐ Not done. Specify reason:				
	☐ Yes ☐ No. Specify reason: ____________________ ☐ Unknown. Specify reason: ____________________		☐ Positive ☐ Negative ☐ Inconclusive ☐ Not done. Specify reason:				

Date of Current Visit	Patient is using at least one effective method of contraception (Check one)	Pregnancy Test Date	Pregnancy Test Result (Check one)	Next Appointment Date	Date of pomalidomide prescription	Physician name (PRINT)	Physician signature
	☐ Yes ☐ No. Specify reason: __________ ☐ Unknown. Specify reason: __________		☐ Positive ☐ Negative ☐ Inconclusive ☐ Not done. Specify reason:				
	☐ Yes ☐ No. Specify reason: __________ ☐ Unknown. Specify reason: __________		☐ Positive ☐ Negative ☐ Inconclusive ☐ Not done. Specify reason:				
	☐ Yes ☐ No. Specify reason: __________ ☐ Unknown. Specify reason: __________		☐ Positive ☐ Negative ☐ Inconclusive ☐ Not done. Specify reason:				

Date of Current Visit	Patient is using at least one effective method of contraception (Check one)	Pregnancy Test Date	Pregnancy Test Result (Check one)	Next Appointment Date	Date of pomalidomide prescription	Physician name (PRINT)	Physician signature
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	☐ Yes ☐ No. Specify reason: _____ ☐ Unknown. Specify reason: _____		☐ Positive ☐ Negative ☐ Inconclusive ☐ Not done. Specify reason:				

[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.

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

▼***This medicinal product is subject to additional monitoring. Healthcare professionals are asked to report any suspected adverse reactions via www.medicinesauthority.gov.mt/adrportal***