Bristol Myers Squibb™

26 Mar 2024

Dear Healthcare Professional,

This letter is to inform you about safety information for prescribing and dispensing the immunomodulatory agents lenalidomide and pomalidomide. This information is regarding the Pregnancy Prevention Program (PPP), and your role(s) as a healthcare professional (HCP) in ensuring that your patients comply with the requirements of the PPP to ensure safe use and handling of these medicines.

Thalidomide is a powerful human teratogen and, if taken during pregnancy, can cause severe birth defects or death to a developing fetus. Lenalidomide and pomalidomide are structurally related to thalidomide. Lenalidomide induced malformations in monkeys similar to those described with thalidomide, and pomalidomide was found to be teratogenic in both rats and rabbits when administered during the period of major organogenesis. If lenalidomide or pomalidomide are given during pregnancy, a teratogenic effect in humans cannot be ruled out. Immunomodulatory agents can pass into seminal fluid. Male patients must also follow the necessary requirements of the PPP to prevent product exposure to a female partner.

As an HCP involved in the care of patients receiving immunomodulatory agents, you must:

- Communicate the benefits and risks of treatment with immunomodulatory agents to your patients
- Provide pregnancy prevention counseling per patient risk categorization at treatment initiation
- Perform a pregnancy test (if applicable) prior to each prescription at every 4 weeks
- Issue patient educational materials to patients, as described below
- Remind patients of the safe use of immunomodulatory agents at each consultation and each time a prescription is dispensed

To ensure that HCPs understand the requirements of the PPP, and that patients receiving immunomodulatory agents are aware of the steps they need to take to comply with the requirements of the PPP, Bristol Myers Squibb (BMS) is providing an informational kit to HCPs, which includes:

- Healthcare Professionals Acknowledgement of Receipt of Educational Materials for Immunomodulatory Agents
- Healthcare Professionals Brochure for Immunomodulatory Agents
- Risk Awareness Form for Counseling Patients Receiving Immunomodulatory Agents
- Patient Agreement Form for Immunomodulatory Agents
- Patient Medication Guide for Immunomodulatory Agents

It is a requirement of the PPP that all HCPs read and understand the **Healthcare Professionals Brochure for Immunomodulatory Agents** before prescribing or dispensing immunomodulatory agents to their patients. Please refer to the **Risk Awareness Form for Counseling Patients Receiving Immunomodulatory Agents** for guidance when counseling patients about the need to avoid pregnancy. The **Patient Agreement Form for Immunomodulatory Agents** is provided to help you ensure that your patients understand the steps needed to comply with the PPP. Please provide patients with the **Patient Agreement Form for Immunomodulatory Agents** and **Patient Medication Guide for Immunomodulatory Agents**. These two resources contain relevant information about the PPP for patients receiving immunomodulatory agents.

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The safe use of immunomodulatory agents is of paramount importance. As part of our ongoing safety monitoring, BMS wishes to be informed of adverse reactions that have occurred during the use of these medicines. Please report any adverse reactions to:

- Email : MedInfo.Singapore@bms.com
- Phone : 1800 415 5182

To confirm that you have received the information kit, please complete the enclosed **Healthcare Professionals Acknowledgement of Receipt of Educational Materials for Immunomodulatory Agents Form** and return this to: Safety_Singapore@bms.com. If you have received the kit directly from a BMS or partner representative, they will complete this form with you.

Please discard any previous educational materials you may have.

Additional copies of these materials can be obtained from local Country Representative.

Please refer to the Pomalyst® Package Insert and Revlimid® Package Insert for the full safety and prescribing information.

If you have any questions or require further information, please contact BMS at Safety_Singapore@bms.com.

Sincerely,



Heather Yoo
Head of Country Patient Safety Southeast Asia

Enclosures:

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- Patient Medication Guide for Immunomodulatory Agents