i-SECURE

Additional Education Material Letter

Imnovid® (Pomalidomide)

Dear Healthcare Professional,

This letter is to inform you about safety information for prescribing and dispensing the immunomodulatory agent pomalidomide. This information is regarding the Pregnancy Prevention. Program (PPP) referred to as i-SECURE in Saudi Arabia, 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.
Please note that there have been some changes to i-SECURE materials, and this information pack should be used for Pomalidomide.

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The Major updates are listed below:
- List of safety concerns have been added to the HCP brochure
- Former HCP letter was renamed to AEMs cover letter
- Patient agreement form with HCP check list was split into two forms: Patient agreement form and Risk awareness form (with inclusion of safety concerns)
- List of side effects were included in the Patient agreement form
- Former Patient brochure was renamed to Patient Card (with inclusion of safety concerns)
- Former HCP registration form was renamed to Prescriber Acknowledgement form

It is therefore necessary that you delete and/or destroy all copies of previous i-SECURE materials.

Thalidomide is a powerful human teratogen and, if taken during pregnancy, can cause severe birth defects or death to a developing fetus. Pomalidomide is structurally related to thalidomide. Pomalidomide was found to be teratogenic in both rats and rabbits when administered during the period of major organogenesis. If pomalidomide is 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 (i-SECURE), 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) and Biologix are providing an informational kit to HCPs, which includes:

- i-SECURE Healthcare Professionals Acknowledgement of Receipt of Educational Materials for Immunomodulatory Agents
- i-SECURE Healthcare Professionals Brochure for Immunomodulatory Agents
- i-SECURE Risk Awareness Form for Counseling Patients Receiving Immunomodulatory Agents
- i-SECURE Patient Agreement Form for Immunomodulatory Agents
- i-SECURE Patient Card for Immunomodulatory Agents
- i-SECURE Product Handling Instructions for Immunomodulatory Agents
- i-SECURE Verification Form

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 Card for Immunomodulatory Agents.** These two resources contain relevant information about the PPP for patients receiving immunomodulatory agents.

Please use the enclosed i- SECURE **Verification Form** to verify patient risk category and if applicable the negative test result, each time you prescribe and dispense an immunomodulatory agent for your patient. This form will serve as a tool to track adherence to PPP requirements and will be collected from each pharmacy on a monthly basis.
For more information on the safe handling of immunomodulatory agents, please refer to the **Product Handling Instructions for Immunomodulatory Agents.**

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

The National Pharmacovigilance Centre (NPC), SFDA:
SFDA Call Center: 19999
E-mail: npc.drug@sfda.gov.sa
Website: https://ade.sfda.gov.sa

Or
LOCAL REPRESENTATIVE OF THE MARKETING AUTHORISATION HOLDER IN KSA
Biologix FZCO, Hibatullah Al Ghaffari Street-Suliemaniah
Kingdom of Saudi Arabia P.O. Box 991, Riyadh 11421 Biologix Pharmacovigilance Department:
E-mail: Pharmacovigilance-ksa@biologixpharma.com
Tel + 966 11 4646 955 Ext 286
Mobile: +966559994037

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 Biologix at Email: Medinfo@biologixpharma.com.

If you have received the kit directly from a Biologix representative, they will complete this form with you.
Additional copies of these materials can be obtained from Biologix upon request at:
Email: medinfo@biologixpharma.com. Please refer to local label for the full safety and prescribing information.

If you have any questions or require further information, please contact Biologix.
Email: medinfo@biologixpharma.com.

Sincerely,
Biologix

Enclosures:
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