Biologix

Bristol Myers Squibb™

i-SECURE

HCP LETTER
Imnovid®(Pomalidomide)

This educational material is part of the marketing authorization and has been approved by the SFDA in August 2023

Dear Healthcare Professional,

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 while prescribing and dispensing the immunomodulatory agent pomalidomide.

Please note that there have been some changes to i-SECURE and this harmonized information pack should be used for pomalidomide.

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.
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 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 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 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, Biologix is providing an informational pack to HCPs, which includes:

- Healthcare Professionals Registration Form
- Healthcare Professionals Brochure for Immunomodulatory Agents
- Patient Agreement Form and Healthcare Professionals Checklist
- Patient Brochure for Immunomodulatory Agents
- Product Handling Instructions for Immunomodulatory Agents
- I-SECURE Verification Form

It is a requirement of the PPP that all HCPs read and understand the **i-SECURE Healthcare Professionals Brochure** before prescribing or dispensing immunomodulatory agents to their patients. Please refer to the **Healthcare Professionals** for guidance when counseling patients about the need to avoid pregnancy. The **i-SECURE Patient Agreement Form** 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 and **Patient Brochure**. 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** located at the end of the Patient Brochure.

The safe use of immunomodulatory agents is of paramount importance. As part of our ongoing safety monitoring, The SFDA, Biologix and BMS 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**
- **Fax: +966-11-205-7662**
- **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 Registration** form and return this to Biologix:

Email: **medinfo@biologixpharma.com**

If you have received the kit directly from a BMS or partner representative, they will complete this form with you.

Additional copies of these materials and the latest SmPC approved in Saudi Arabia can be obtained from Biologix (contact details given above). Please refer to the SmPC for the full safety and prescribing information.

If you have any questions or require further information, please contact Biologix.

Sincerely,
Biologix

Enclosures:

a. i-SECURE HCP Registration Form
b. i-SECURE HCP Brochure
c. i-SECURE Patient Agreement Form and HCP Checklist
d. i-SECURE Patient Brochure
e. i-SECURE Product Handling Instructions for Immunomodulatory Agents
f. i-SECURE Verification Form

*Please note that in accordance with applicable laws and regulations, Biologix has the obligation to disclose to Saudi Food and Drug Authority (SFDA) name, contact details and any transfer of value to Healthcare Professional or Healthcare Organization.