i-SECURE

Imnovid® (Pomalidomide)

i-SECURE PATIENT CARD FOR IMMUNOMODULATORY AGENTS

Patient Card for Immunomodulatory Agents

You have been prescribed an immunomodulatory agent. This type of treatment can cause birth defects. It is extremely important that you do not take them if you are pregnant or planning to become pregnant. If you are able to become pregnant and are not using an effective contraceptive (birth control) method, do not use this treatment. This patient card is to help ensure safe use and handling of the immunomodulatory agent.
If used during pregnancy, the immunomodulatory agent, pomalidomide, can harm the developing fetus. Potential risks include loss of the fetus and birth defects. Please make sure that you have read and understood the following information prior to starting treatment with immunomodulatory agents. If you have any questions or concerns about your treatment, please reach out to your healthcare professional.

For all patients:

- You should never share your immunomodulatory agents with anyone else.
- You should store immunomodulatory agents safely so that no-one else can take the medicine by accident. Ensure that immunomodulatory agent is out of reach of children.
- You should not open, crush, or overly handle the capsules.
- You should always dispose of any unused capsules according to local regulations, at the end of your treatment.
- For more information on safe handling of the immunomodulatory agent, please refer to the Product Handling Instructions for Immunomodulatory Agents.
- You should not donate blood during treatment, even during dose interruptions, or for at least 7 days after stopping treatment.
- If you experience any side effects while taking immunomodulatory agents, you should tell your healthcare professional.
- For additional information, please refer to the patient information Leaflet.
- You must never take immunomodulatory agents if:

a) You are pregnant, or
b) You are able to become pregnant, even if you are not planning to, unless all of the conditions of the Pregnancy Prevention Program are met

If you are a woman who is able to become pregnant:

- You must use at least one effective method of contraception for at least 4 weeks before starting treatment, throughout the duration of your treatment, even during dose interruptions, and for at least 4 weeks after stopping treatment. Your healthcare professional will advise you on appropriate methods of contraception. Some types of contraception are not recommended during treatment with immunomodulatory agents. That's why it's essential that you discuss this with your healthcare professional. The following methods are examples of effective contraception:
- Implant
- Levonorgestrel-releasing intrauterine system (IUS)
- Medroxyprogesterone acetate depot

- Tubal sterilisation
- Sexual intercourse with a vasectomised male partner only; vasectomy must be confirmed by two negative semen analyses
- Ovulation inhibitory progesterone-only pills (i.e. desogestrel) **AND**

- *You will have pregnancy tests under the supervision of your healthcare professional before treatment. These will be repeated at least every 4 weeks during treatment, even during dose interruptions, and at least 4 weeks after the treatment has finished (unless it is confirmed that you have had a tubal sterilization), even if you confirm absolute and continuous sexual abstinence from heterosexual intercourse on a monthly basis.*
- You should start treatment with your immunomodulatory agent as soon as possible after a negative pregnancy test result and having received your medication.
- If you become pregnant while on immunomodulatory agents, you must stop treatment immediately and inform your healthcare professional immediately. They may recommend that you see a type of healthcare professional specializing in developmental abnormalities of the fetus.

If you are a male:

- You must use condoms even if you have had a vasectomy as seminal fluid may still contain the product in the absence of spermatozoa, throughout the duration of your treatment, even during dose interruptions, and for at least 7 days after stopping treatment if your partner is pregnant or can become pregnant and not using effective contraception.
- You must not donate semen or sperm during treatment, even during dose interruptions, and for at least 7 days after stopping treatment as immunomodulatory agents can pass into seminal fluid.
- You should inform your treating healthcare professional immediately if your partner becomes pregnant while you are taking or within 7 days after you have stopped taking immunomodulatory agents. Your partner should inform her healthcare professional immediately. It is recommended that she be referred to a healthcare professional specializing in abnormalities of the fetus for evaluation and advice.

For more information about the effects and side effects of your treatment, please refer to the *Patient Information Leaflet.*

Side Effects

Like all medicines, side effects may be experienced, although not everybody gets them. Some side effects are more common than others and some are more serious than others. Ask your doctor or pharmacist if you would like more information and refer to the patient information leaflet for the product you are prescribed **Pomalidomide**.

Call your doctor immediately if you experience any signs or symptoms or if they get worse.

The following are NOT all the possible signs and symptoms of side effects from treatment with **Pomalidomide**:

- Heart palpitations or fast heartbeat, chest pains, dizziness or fainting, shortness of breath, weakness, blurred vision, tiredness, or reduced ability to exercise.
- Bleeding (including nosebleeds) or bruising more easily than normal.
- The number of platelets (cells which are responsible for making the blood clot properly) can be reduced.
- Your doctor may monitor your blood cell numbers during treatment and do some blood tests regularly and will check your general condition to make sure the medicine is working and may adjust your dose accordingly.

For a complete list of side effects, please refer to each individual Patient information leaflet.

You must talk to your doctor if you have any side effects during your treatment with **Pomalidomide**.

IMPORTANT CONTACT INFORMATION

I have been prescribed ……<insert brand name>

My Doctor's Contact Information:

The healthcare professional treating this patient should complete the 'My Doctor's Contact Information' section of this Patient Alert Card

Please complete this form in BLOCK CAPITAL LETTERS.	
First Name	
Last Name	
Institution Name and Phone	
After-Hours Phone	

My Contact Information:

Please complete this form in BLOCK CAPITAL LETTERS.	
My name and Phone	
Emergency Contact (name and phone)	

Data Privacy Notice

Your personal data will be processed by Biologix for the purposes of administering the i-SECURE program, on behalf of Bristol-Myers Squibb (BMS).

We may share your data with BMS entities and third parties providing services to BMS for the management of the program and administration purposes. This may entail the transfer of your data to other countries such as the USA and Switzerland. BMS will implement appropriate contractual, organizational, and technical security measures to protect your information from unauthorized access, use or disclosure. If required, we may share your data with health authorities for safety and other regulatory reasons.

For more information on how your personal data is being processed, contact **Biologix at BX-Privacy-KSA@biologixpharma.com**

REPORTING OF ADVERSE REACTIONS

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:

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 Gha_ari
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: +966 55 9994 037