Biologix

Bristol Myers Squibb™

i-SECURE

Healthcare Professionals Brochure for Immunomodulatory Agent Imnovid®(Pomalidomide)

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

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Important Risk Minimization Information for Healthcare Professionals

THE PREGNANCY PREVENTION PROGRAM (I-SECURE) AT A GLANCE

This brochure contains safety information for prescribing and dispensing the immunomodulatory agent pomalidomide, with regard to the Pregnancy Prevention Program (PPP), to ensure safe use and handling of the product. This brochure addresses only the teratogenic risk and pregnancy prevention requirements for immunomodulatory agents. Please refer to the local label for the full safety and prescribing information, available on request from Biologix:

Email: medinfo@biologixpharma.com

Healthcare professionals must:

- Communicate the benefits and risks of treatment with immunomodulatory agents to their 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

PREGNANCY PREVENTION PROGRAM (I-SECURE)

The PPP was developed to help healthcare professionals (HCPs) and patients understand the risks of immunomodulatory agents and pregnancy. These materials provide a comprehensive overview of how the PPP prevents birth defects and exposure of thalidomide and pomalidomide to fetuses.

- Thalidomide is a powerful human teratogen and, if taken during pregnancy, can cause severe birth defects or death to a developing fetus. In the 1950s and 1960s, thalidomide was prescribed to pregnant women as a sedative and to relieve morning sickness. Consequently, approximately 12000 children were born with severe birth defects caused by thalidomide.
  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 are contraindicated in pregnancy and in female patients of childbearing potential unless all of the conditions of the PPP, as described in this brochure, are met.

- Immunomodulatory agents can pass into seminal fluid. Male patients must also follow the necessary requirements of the PPP to prevent exposure to a female partner.
- It is a requirement of the PPP that all HCPs ensure that they have read and understood this brochure before prescribing or dispensing immunomodulatory agents to their patients.
- At treatment initiation, all male patients and all female patients of childbearing potential should undergo counseling about the need to avoid pregnancy. A counseling checklist (Healthcare Professionals Checklist) is appended to this document to guide HCPs through the fulfillment of the PPP requirements. Please use the Patient Agreement Form for Immunomodulatory Agents to document patient understanding.
- Healthcare professionals are advised to refer to the Healthcare Professionals Checklist for more information about ensuring that patients receiving treatment with immunomodulatory agents are aware of the requirements of the PPP and the steps required for compliance.
- Patients should be capable of complying with the requirements for safe use of immunomodulatory agents.
- Prior to treatment initiation, patients and HCPs must fill out and/or be provided with the i-SECURE Patient Agreement Form and i-SECURE Patient Brochure. These materials will provide the relevant information to patients receiving treatment with immunomodulatory agents.
- Completion of the i-SECURE Verification Form is mandatory at the time of each prescription, for all patients. The patient must present this form to the pharmacy, along with the prescription, or the prescriber may send the form directly to the pharmacy with each prescription. This form enables the prescriber to inform the pharmacist of patient risk category and to verify the pregnancy test result (if applicable) and will be collected from the pharmacy by Biologix on a monthly basis.
- The description of the PPP and the categorization of patients based on sex and childbearing potential is described in the algorithm (attached).

For more information about prescribing and dispensing immunomodulatory agents, including the recommended dosing schedule and duration, consult the local label.

Guidance for All Patients

Patients must be informed not to donate blood during treatment and for at least 7 days after cessation of treatment with immunomodulatory agents. Any unused medication at the end of treatment must be disposed of as per local regulations.

Patients must understand that their treatment is only for them and it:

- Must not be shared with anyone else, even if they have similar symptoms
- Must be stored away safely so that no-one else can take the medicine by accident
- Must be kept out of reach of children

Patients must also understand that they should not open, crush, or overly handle the capsules. For more information on safe handling of immunomodulatory agents, please refer to the Product Handling Instructions for Immunomodulatory Agents.

Determining Childbearing Potential

Prior to treatment, female patients of childbearing potential must be informed about the risks and precautions associated with immunomodulatory agents, including potential risk of birth defects and the need for pregnancy prevention during and following discontinuation of treatment. Please refer to the Healthcare Professionals Checklist for additional guidance.

To determine if a female patient is not of childbearing potential, please refer to the below guidelines and refer the patient for a gynecological opinion if you are uncertain.

1. Females ≥ 50 years old and naturally amenorrhoeic for ≥ 1 year
- Amenorrhoea following cancer therapy does not rule out childbearing potential
2. Females that have premature ovarian failure confirmed by a gynecologist
3. Females that have not begun menstruation
4. Females with bilateral salpingo-oophorectomy or hysterectomy
5. Females with XY genotype, Turner's syndrome or uterine agenesis

A female patient must never take immunomodulatory agents if she is pregnant.

PPP Guidance for Female Patients of Childbearing Potential

Female patients of childbearing potential are required to have a negative pregnancy test and at least 4 weeks of effective contraceptive use or commit to absolute and continuous abstinence from heterosexual intercourse prior to beginning treatment.

A female patient must never take immunomodulatory agents if they are able to become pregnant, even if not planning to become pregnant, unless all of the conditions of the PPP are met

In view of the teratogenic risk associated with immunomodulatory agents, fetal exposure should be avoided.

- Female patients of childbearing potential (even if they have amenorrhea or irregular menstrual periods) must:

– use at least one effective method of contraception for at least 4 weeks before, during, and until at least 4 weeks after cessation of treatment with immunomodulatory agents, and even in case of dose interruption, or
– commit to absolute and continuous abstinence from heterosexual intercourse during the entire period of risk associated with immunomodulatory agents. The reliability of sexual abstinence needs to be evaluated by the HCP in relation to the duration of use of treatment with immunomodulatory agents and the preferred and usual lifestyle of the patient and be confirmed on a monthly basis. The HCP should document this each month in the patient's medical records.

AND

– have a medically supervised negative pregnancy test (with a minimum sensitivity of 25 mIU/mL) once contraception has been established for at least 4 weeks prior to treatment initiation, at least every 4 weeks during treatment (this includes dose interruptions) and at least 4 weeks after the end of treatment (unless confirmed tubal sterilization). This includes female patients of childbearing potential who confirm absolute and continuous abstinence from heterosexual intercourse during the entire period of risk associated with immunomodulatory agents.

- Patients should be advised to inform the HCP prescribing her contraception about the immunomodulatory agent.

- Patients should be advised to inform the HCP prescribing her immunomodulatory agent if a change or cessation in method of contraception is needed.

A patient not established on effective contraception must be referred to an appropriately trained HCP for contraceptive advice in order that contraception can be initiated.

The following methods are examples of effective contraception:

- implant, levonorgestrel-releasing intrauterine system, medroxyprogesterone acetate depot, tubal s terilization, sexual intercourse with a vasectomized male partner only (vasectomy must be confirmed by two negative semen analyses), and ovulation inhibitory progesterone-only pills (i.e. desogestrel)

Because of the increased risk of venous thromboembolism in patients with multiple myeloma, combined oral contraceptive pills are not recommended. If a patient is currently using combined oral contraception, the patient should switch to one of the effective methods listed above. The risk of venous thromboembolism continues for 4 to 6 weeks after discontinuing combined oral contraception.

Patients should be advised to inform their HCP of a missed menstrual period, any unusual menstrual bleeding, or if she believes that she may be pregnant. If a pregnancy does occur while receiving treatment with immunomodulatory agents, treatment must be discontinued, and the HCP informed immediately. Refer the patient to an HCP specialized in teratology for evaluation and advice.

Requirements in the Event of a Suspected Pregnancy or Exposure of a Pregnant Partner

- If female patient, stop treatment immediately and inform the HCP immediately.
- Refer female patient to an HCP specialized or experienced in teratology for evaluation and advice.
- If male patient, inform treating HCP immediately if female partner becomes pregnant while he is on, or within 7 days after he has stopped receiving treatment with immunomodulatory agents.
- Notify SFDA or Biologix of all such occurrences:
  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
- 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

BMS and Biologix will wish to follow up with you regarding the progress of all suspected pregnancies in female patients or partners of male patient cases.

PPP Guidance for Male Patients

- In view of the teratogenic risk associated with immunomodulatory agents, fetal exposure should be avoided.
- Prior to treatment, male patients must be informed about the risks and precautions associated with immunomodulatory agents, including potential risk of birth defects and the need for pregnancy prevention during and following discontinuation of treatment. Please refer to the Healthcare Professionals Checklist for additional guidance.
- Pomalidomide have been detected in seminal fluid. Therefore, all male patients should use condoms throughout treatment duration, during dose interruptions, and for at least 7 days after cessation of treatment if his partner is pregnant or of childbearing potential and is not using effective contraception (even if the male patient has undergone vasectomy).
- Inform patients which effective contraceptive methods his female partner can use.

- Instruct patients that if his partner becomes pregnant while he is on treatment with immunomodulatory agents or within 7 days after medication has been discontinued, the HCP should be informed immediately. His partner should inform her HCP immediately. It is recommended that she be referred to an HCP specialized in teratology for evaluation and advice.

- Male patients should not donate blood during treatment, even during dose interruptions, or for at least 7 days following discontinuation of treatment.

- Male patients should not donate semen or sperm during treatment, including during dose interruptions and for at least 7 days following discontinuation of treatment as immunomodulatory agents can pass into seminal fluid.

REPORTING OF ADVERSE REACTIONS

The safe use of immunomodulatory agents is of paramount importance. As part of our ongoing safety monitoring, 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

CONTACT DETAILS

For information and questions on the risk management of BMS's products and the PPP, contact Biologix:
Email: medinfo@biologixpharma.com

Patient Risk Categorization, Pregnancy Test and Contraception Requirements Algorithm