Biologix

Bristol Myers Squibb™

i-SECURE

Patient Agreement Form and HCP Checklist Imnovid®(Pomalidomide)

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

Introduction

This form must be completed for each patient prior to the initiation of treatment with immunomodulatory agents. A separate copy should be filled out per product, specifying which immunomodulatory agent the patient is receiving. Both the healthcare professional and patient must fill out parts of this form. A copy is kept in the patient medical record, and the other copy is provided to the patient together with the i-SECURE Patient Brochure.
This patient is receiving:

☐ Pomalidomide

The aim of this form is to ensure patients are aware of the risks associated with product exposure to a developing fetus and understand the risk of teratogenicity associated with use of immunomodulatory agents. It is also to aid healthcare professionals in counseling their patient on this risk, as well as the steps necessary to mitigate the risk. It is not a contract and does not absolve anyone from their responsibilities with regard to the safe use of the product and prevention of fetal exposure to immunomodulatory agents.

Warning: 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. The conditions of the Pregnancy Prevention Program (PPP) must be fulfilled for female patients unless there is reliable evidence that the patient is not of childbearing potential. 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.

Healthcare professionals are advised that the following checklists are intended to be used to ensure patient understanding of the requirements of the PPP prior to initiation of treatment. Separate checklists are provided per patient risk categorization: female patients of childbearing potential, male patients, and female patients not of childbearing potential. For more information, please refer to the Healthcare Professionals Brochure for Immunomodulatory Agents. Please choose the applicable patient risk categorization below for each patient and refer to the counseling messages provided.

For the full safety and prescribing information, please refer to the local label.

TO BE COMPLETED BY THE PRESCRIBER

PATIENT DETAILS

Please complete this form in BLOCK CAPITAL LETTERS.

Patient's First Name	
Patient's Last Name	
Date of Birth	
Patient's Risk Categorization	☐ Female Patient of Childbearing Potential ☐ Male Patient ☐ Female Patient Not of Childbearing Potential
Counseling Date	

HCP CHECKLIST

Did you inform your patient:

	Add 'X' if done		
	Male Patients	**Female of non-childbearing potential**	**Female of childbearing potential**
Of the expected teratogenic risk to the unborn child?			
Not to share medication?			
To dispose of unused capsules at the end of treatment as per local regulations?			
To not open, crush, or overly handle the capsules?			
To store immunomodulatory agents safely so that no-one else can take the medicine by accident and that they must keep the capsules out of reach of children?			
Not to donate blood while receiving immunomodulatory agents, during treatment interruptions, and for at least 7 days following treatment discontinuation?			
Of the need to use at least one effective method of contraception for at least 4 weeks before starting treatment, throughout the entire duration of treatment, including during treatment interruptions, and for at least 4 weeks after the end of treatment,	N/A	N/A	

HCP CHECKLIST Did you inform your patient:	Add 'X' if done		
	MALE	Female of non-childbearing potential	Female of childbearing potential
Or confirm monthly absolute and continuous abstinence from heterosexual intercourse? The following methods are examples of effective contraception: Implant, levonorgestrel-releasing intrauterine system, medroxyprogesterone acetate depot, tubal sterilization, 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)			
That periodic abstinence (calendar, symptothermal, and post-ovulation methods), withdrawal (coitus interruptus), spermicides only, and lactational amenorrhea method are not acceptable methods of absolute and continuous abstinence?	N/A	N/A	
To comply with advice regarding contraception, even if she has amenorrhea or irregular menstrual periods?	N/A	N/A	
Which effective contraceptive methods (listed above) can be used by the patient or the female partner of a male patient?		N/A	
Of the expected consequences of pregnancy and the need to consult rapidly if there is a risk of pregnancy?		N/A	
The need to stop treatment immediately if pregnancy is suspected?		N/A	
The need to inform her HCP immediately if she is pregnant / female partner of a male patient becomes pregnant during or within 7 days ≥ after treatment cessation?		N/A	
Of the need to inform the HCP prescribing her contraception about the immunomodulatory agent?	N/A	N/A	
Of the need to inform the HCP prescribing her immunomodulatory agent if a change or cessation in method of contraception is needed?	N/A	N/A	

HCP CHECKLIST Did you inform your patient:	MALE	Female of non-childbearing potential	Female of childbearing potential
		Add 'X' if done	
To use condoms, even for those who have had a vasectomy, as seminal fluid may still contain immunomodulatory agents in the absence of spermatozoa throughout treatment duration; during dose interruptions; and for at least 7 days after cessation of treatment if partner is pregnant or of childbearing potential and not using effective contraception?		N/A	N/A
Not to donate semen or sperm during treatment, during dose interruptions, and for at least 7 days following treatment discontinuation as immunomodulatory agents can pass into seminal fluid?		N/A	N/A
Can you confirm that your patient:	MALE	Female of non-childbearing potential	Female of childbearing potential
Was referred to a contraceptive consultant, if required?	N/A	N/A	
Is capable of complying with contraceptive measures?		N/A	
Agreed to undergo pregnancy testing at least once every 4 weeks and at least 4 weeks after the end of treatment unless confirmed tubal sterilization?	N/A	N/A	
Had a negative pregnancy test before starting treatment even if practicing absolute and continuous abstinence from heterosexual intercourse?	N/A	N/A	

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

Prescriber Confirmation

I confirm that I have fully explained to the patient named above the nature, purpose, and risks of the treatment associated with immunomodulatory agents and the need for compliance with the conditions of the PPP using the Healthcare Professionals Checklist for conseling patients receiving immunomadulatory Agents.By sgning this from, i consent to the processing of my personal data.

PRESCRIBER DETAILS

Please complete this form in BLOCK CAPITAL LETTERS.

Prescriber's First Name	
Prescriber's Last Name	
Prescriber's Institution Name	
Prescriber's Signature	
Date	DD/MM/YYYY

TO BE COMPLETED BY THE PATIENT

For Female Patients of Childbearing Potential: please read thoroughly. If you agree, mark an X by the statement. It is important that you complete this checklist in order to receive treatment.

I AGREE THAT	Add 'X' if Agree
I have been fully informed by my healthcare professional about the nature, purpose, and risks of the treatment associated with immunomodulatory agents.	
I understand that severe birth defects may occur with immunomodulatory agents. I have been informed by my healthcare professional and understand that any fetus has a high risk of birth defects and could even die if a woman is pregnant or becomes pregnant while taking such medicines.	
I understand that I must not receive immunomodulatory agents if I am pregnant or plan to become pregnant.	
I understand that I must use at least one effective method of contraception for at least 4 weeks before starting treatment, throughout the entire duration of treatment, even during dose interruptions, and for at least 4 weeks after stopping treatment, even if I have amenorrhea (lack of menstrual periods) or irregular menstrual periods. The following methods are examples of effective contraception: • Implant, levonorgestrel-releasing intrauterine system, medroxyprogesterone acetate depot, tubal sterilization, sexual intercourse with a vasectomized male partner only (vasectomy must be confirmed by two negative semen analyses), and ovulation inhibitory progesterone-only pills The need for contraception does not apply to patients who confirm monthly absolute and continuous abstinence from heterosexual intercourse.	
I understand that if I need to change or stop my method of contraception, I will discuss this first with: • the healthcare professional prescribing my immunomodulatory treatment; AND • the healthcare professional prescribing my contraception	
I understand that before starting treatment with immunomodulatory agents, I must have a pregnancy test. I will then have a pregnancy test at least every 4 weeks during treatment and a test at least 4 weeks after stopping treatment, even if I confirm monthly absolute and continuous abstinence.	

I AGREE THAT	Add 'X' if Agree
I understand that periodic abstinence (calendar, symptothermal, and post-ovulation methods), withdrawal (coitus interruptus), spermicides only, and the lactational amenorrhea (the absence of a menstrual period during breastfeeding) method are not acceptable methods of absolute and continuous abstinence.	
I understand that I must immediately stop taking immunomodulatory agents and inform my healthcare professional immediately if I become pregnant while taking such medicines; or if I miss my menstrual period or experience any unusual menstrual bleeding; or think FOR ANY REASON that I may be pregnant.	
I understand that immunomodulatory agents will be prescribed ONLY for me. I must not share them with ANYONE.	
I understand that I must store immunomodulatory agents safely so that no-one else can take the medicine by accident and that they must be kept out of reach of children.	
I understand that I must not open, crush, or overly handle the immunomodulatory agent.	
I know that I cannot donate blood while receiving immunomodulatory agents, even during dose interruptions, and for at least 7 days after stopping treatment.	
I have received the Patient Brochure for Immunomodulatory agents.	

I understand that I must dispose of any unused medication as per local regulations at the end of my treatment.

This form will be kept by your doctor and will be kept in your medical file, for the purposes of compliance with the risk management plan needed for the medicinal product that has been prescribed to you. A copy of this form will be given to you.

Patient Confirmation

I confirm that I understand and will comply with the requirements of the PPP and I agree that my healthcare professional can initiate my treatment.

By signing this form, I consent to the processing of my personal data.

Patient's Signature	
Date	DD/MM/YYYY

TO BE COMPLETED BY THE PATIENT

For Male Patients: please read thoroughly. If you agree, mark an X by the statement. It is important that you complete this checklist in order to receive treatment.

I AGREE THAT	Add 'X' if Agree
I have been fully informed by my healthcare professional about the nature, purpose, and risks of the treatment associated with immunomodulatory agents.	
I understand that severe birth defects may occur with immunomodulatory agents. I have been informed by my healthcare professional and understand that any fetus has a high risk of birth defects and could even die if a woman is pregnant or becomes pregnant while taking such medicines.	
I understand that immunomodulatory agents pass into seminal fluid. If my partner is pregnant or able to become pregnant, and she does not use effective contraception, I must use condoms throughout the duration of my treatment, even during dose interruptions, and for at least 7 days after stopping treatment, even if I have had a vasectomy.	
I have been informed which effective contraceptive methods may be appropriate for a female partner of a male patient. The following methods are examples of effective contraception: • implant, levonorgestrel-releasing intrauterine system, medroxyprogesterone acetate depot, tubal sterilization, 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)	
I understand that if my partner does become pregnant while I am receiving immunomodulatory agents, or within 7 days after I have stopped taking such medicines, I should inform my healthcare professional immediately, and my partner should also consult her healthcare professional immediately.	
I understand that immunomodulatory agents will be prescribed ONLY for me. I must not share them with ANYONE.	
I understand that I must store immunomodulatory agents safely so that no-one else can take the medicine by accident and that they must be kept out of reach of children.	

I AGREE THAT	Add 'X' if Agree
I understand that I must not open, crush, or overly handle the immunomodulatory agent.	
I know that I cannot donate blood while receiving immunomodulatory agents, even during dose interruptions, or for at least 7 days after stopping treatment.	
I know that I cannot donate semen or sperm while receiving immunomodulatory agents, even during dose interruptions, and for at least 7 days after stopping treatment as immunomodulatory agents can pass into seminal fluid.	
I have received the Patient Brochure for Immunomodulatory agents.	
I understand that I must dispose of any unused medication as per local regulations at the end of my treatment.	

This form will be kept by your doctor and will be kept in your medical file, for the purposes of compliance with the risk management plan needed for the medicinal product that has been prescribed to you. A copy of this form will be given to you.

Patient Confirmation

I confirm that I understand and will comply with the requirements of the PPP and I agree that my healthcare professional can initiate my treatment.

By signing this form, I consent to the processing of my personal data.

Patient's Signature	
Date	DD/MM/YYYY

TO BE COMPLETED BY THE PATIENT

For Female Patients Not of Childbearing Potential: please read thoroughly. If you agree, mark an X by the statement. It is important that you complete this checklist in order to receive treatment.

I AGREE THAT	Add 'X' if Agree
I have been fully informed by my healthcare professional about the nature, purpose, and risks of the treatment associated with immunomodulatory agents.	
I understand that severe birth defects may occur with immunomodulatory agents. I have been informed by my healthcare professional and understand that any fetus has a high risk of birth defects and could even die if a woman is pregnant or becomes pregnant while taking such medicines.	
I understand that immunomodulatory agents will be prescribed ONLY for me. I must not share them with ANYONE.	
I understand that I must store immunomodulatory agents safely so that no-one else can take the medicine by accident and that they must be kept out of reach of children.	
I understand that I must not open, crush, or overly handle the immunomodulatory agent.	
Il know that I cannot donate blood while receiving immunomodulatory agents, even during dose interruptions, and for at least 7 days after stopping treatment.	
I have received the Patient Brochurefor Immunomodulatory agents.	
I understand that I must dispose of any unused medication as per local regulations at the end of my treatment.	

Patient Confirmation

I confirm that I understand and will comply with the requirements of the PPP and I agree that my healthcare professional can initiate my treatment.

By signing this form, I consent to the processing of my personal data.

Patient's Signature	
Date	DD/MM/YYYY