i-SECURE

Imnovid® (Pomalidomide)

RISK AWARENESS FORM FOR COUNSELING PATIENTS RECEIVING IMMUNOMODULATORY AGENTS

Risk Awareness Form for Counseling Patients Receiving Immunomodulatory Agents

This Risk Awareness Form is to assist healthcare professionals (HCPs) counseling a patient prior to initiating treatment with immunomodulatory agents (Pomalidomide), to ensure that patients receiving immunomodulatory agents are aware of the Pregnancy Prevention Program (PPP) requirements and the necessary steps to comply. 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. Prior to initiation of treatment, provide your patients with the patient educational materials (Patient Agreement Form for Immunomodulatory Agents, Patient Card for Immunomodulatory Agents and product Handling Instructions for Immunomodulatory agents)

PATIENT DETAILS
Please complete this form in BLOCK CAPITAL LETTERS.

Patient's First Name	
Patient's Last Name	
Patient's Signature	
Counseling Date	

PRESCRIBER DETAILS
Please complete this form in BLOCK CAPITAL LETTERS.

Prescriber's First Name	
Prescriber's Last Name	
Prescriber's Signature	
Date	

FOR ALL PATIENTS:

Did you inform your patient:	Add '✓' if done
1) Of the expected teratogenic risk to the developing fetus?	
2) Not to share medication?	
3) To dispose of unused capsules at the end of treatment as per local regulations?	
4) To not open, crush, or overly handle the capsules?	
5) 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?	
6) Not to donate blood while receiving immunomodulatory agents, during treatment interruptions, and for **at least 7 days** following treatment discontinuation?	

Please refer to Healthcare Professionals Brochure for Immunomodulatory Agents for criteria to determine if female patient is not of childbearing potential and for information on effective contraception while receiving immunomodulatory agents. For full safety and prescribing information, please refer to the ***Local label.***

FOR FEMALE PATIENTS OF CHILDBEARING POTENTIAL:

Did you inform your patient:	Add '✓' if done
1) 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, **or confirm monthly** absolute and continuous abstinence from heterosexual intercourse? 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) The need for contraception does not apply to patients who confirm monthly absolute and continuous abstinence from heterosexual intercourse.	
2) 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?	
3) To comply with advice regarding contraception, even if she has amenorrhea or irregular menstrual periods?	
4) Which effective contraceptive methods can be used?	
5) Of the expected consequences of pregnancy and the need to consult rapidly if there is a risk of pregnancy?	
6) The need to stop treatment immediately if pregnancy is suspected?	
7) The need to inform her HCP immediately if she is pregnant?	
8) Of the need to inform the HCP prescribing her contraception about the immunomodulatory agent?	
9) Of the need to inform the HCP prescribing her immunomodulatory agent if a change orcessation in method of contraception is needed?	
Can you confirm that your patient:	
1)Was referred to a contraceptive consultant, if required?	
2) Is capable of complying with contraceptive measures?	
3) 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?	
4) Had a negative pregnancy test before starting treatment even if practicing absolute and continuous abstinence from heterosexual intercourse?	

FOR MALE PATIENTS:

Did you inform your patient:	Add '✓' if done
1) 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 (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)	
2) Of the expected consequences of pregnancy and the need to consult rapidly if there is a risk of pregnancy?	
3) To inform his treating HCP immediately if his partner becomes pregnant during or **within 7 days** after treatment cessation?	
4) 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?	
5) 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?	
Can you confirm that your patient:	
1) Is capable of complying with contraceptive measures?	

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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**