• PREGNANCY PREVENTION PROGRAM •

# RISK AWARENESS FORM FOR COUNSELING PATIENTS

## RECEIVING IMMUNOMODULATORY AGENTS

Revlimid® (Lenalidomide) and Pomalyst® (Pomalidomide)

This Risk Awareness Form is to assist healthcare professionals (HCPs) counseling a patient prior to initiating treatment with immunomodulatory agents (lenalidomide and 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 and Patient Medication Guide for Immunomodulatory Agents).

| PATIENT DETAILS | PRESCRIBER DETAILS |
|---|---|
| • Please complete this form in BLOCK CAPITAL LETTERS. | • Please complete this form in BLOCK CAPITAL LETTERS. |
| Patient's First Name : | Prescriber's First Name : |
| Patient's Last Name : | Prescriber's Last Name : |
| Patient's Signature : | Prescriber's Signature : |
| Counseling Date : | Date : |

## For All Patients

| Did you inform your patient: | Add 'X' if done |
|---|---|
| Of the expected teratogenic risk to the developing fetus? | |
| Not to share medication? | |
| To return of unused capsules at the end of treatment to their pharmacist for safe disposal? | |
| To not open, crush, or overly handle the capsules? | |
| To store lenalidomide and pomalidomide 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 lenalidomide and pomalidomide, 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 lenalidomide and pomalidomide. For the full safety and prescribing information, please refer to Pomalyst® Package Insert and Revlimid® Package Insert.

## For Female Patients of Childbearing Potential

| Did you inform your patient: | Add 'X' if done |
|---|---|
| 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:<br>• 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? | |
| To comply with advice regarding contraception, even if she has amenorrhea or irregular menstrual periods? | |
| Which effective contraceptive methods can be used? | |
| Of the expected consequences of pregnancy and the need to consult rapidly if there is a risk of pregnancy? | |
| The need to stop treatment immediately if pregnancy is suspected? | |
| The need to inform her HCP immediately if she is pregnant? | |
| Of the need to inform the HCP prescribing her contraception about the lenalidomide or pomalidomide ? | |
| Of the need to inform the HCP prescribing her lenalidomide or pomalidomide if a change or cessation in methods of contraception is needed? | |
| Can you confirm that your patient: | |
| Was referred to a contraceptive consultant, if required? | |
| Is capable of complying with contraceptive measures? | |
| 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? | |
| 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 'X' if done |
|---|---|
| Which effective contraceptive methods may be appropriate for a female partner of a male patient? The following methods are examples of effective contraception:<br>• 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) | |
| Of the expected consequences of pregnancy and the need to consult rapidly if there is a potential of pregnancy? | |
| To inform his treating HCP immediately if his partner becomes pregnant during treatment or within 7 days after treatment cessation? | |
| To use condoms, even for those who have had a vasectomy, as seminal fluid may still contain lenalidomide or pomalidomide 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? | |
| Not to donate semen or sperm during treatment, during dose interruptions, and for at least 7 days following treatment discontinuation as lenalidomide and pomalidomide can pass into seminal fluid? | |
| Can you confirm that your patient: | |
| Is capable of complying with contraceptive measures? | |