Pomalidomide SPC® (Pomalidomide)

Combined Checklist for Commencing (Pomalidomide)

*This document has been reviewed and approved by The **Saudi Food and Drug Authority (SFDA).***
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This checklist is to assist you with counselling a patient before they commence pomalidomide treatment in order to assure it is used safely and correctly. Please choose the applicable column for the risk category of the patient and refer to the counselling messages provided.

Counselling	Women of Childbearing Potential	Women of Non-Childbearing Potential*	Male
inform expected teratogenic risk to the unborn child	●	●	●
Inform of the need for effective 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 absolute and continued abstinence	●		
Inform that even if patient has amenorrhoea they must comply with advice no contraception	●		
Confirm patient is capable of complying with contraceptive measures	●		●
Inform of the expected consequences of pregnancy and the need to consult rapidly if there is a risk of pregnancy	●		●
Inform of the need to stop treatment immediately if female patient is suspected to be pregnant	●		
Confirm patient agrees to undergo pregnancy testing at least in 4 weekly intervals unless confirmed tubal sterilisation	●		
Inform of hazards and necessary precautions associated with use of pomalidomide	●	●	●
Inform patient not to share medication	●	●	●
Inform to return unused capsules to pharmacist	●	●	●
Inform not to donate blood whilst taking pomalidomide, during treatment interruptions and for at least 7 days following discontinuation	●	●	●
Inform of the need to use condoms, including those who have had a vasectomy as seminal fluid may still contain pomalidomide in the absence of spermatozoa, throughout treatment duration, during dose interruption, and for at least 7 days after cessation of treatment if partner is pregnant or of childbearing potential not using effective contraception			●
Inform of the need not to donate semen or sperm during treatment, during dose interruptions, and for at least 7 days following discontinuation			●
Inform about the thromboembolic risk and possible requirement to take thromboprophylaxis during treatment with pomalidomide	●	●	●
Inform about which are effective contraceptive methods that she or the female partner of a male patient can use	●		●
Inform that if his female partner becomes pregnant whilst he is taking pomalidomide or shortly after he has stopped taking pomalidomide, he should inform his prescriber immediately and that it is recommended to refer the female partner to a physician specialised or experienced in teratology for evaluation and advice			●

*** Refer to Healthcare Professional brochure for criteria to determine if patient is a woman of non-childbearing potential.**
****Refer to Healthcare Professional brochure for information on contraception.**

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Contraceptive Referral

	Women of Childbearing Potential	Women of Non-Childbearing Potential*	Male
contraceptive referral required	●		
contraceptive referral made	●		
contraceptive constitution completed	●		

Contraception

Patent is currently established on one of the following for at least 4 weeks

	Women of Childbearing Potential	Women of Non-Childbearing Potential*	Male
implat	●		
levonorgestrel-releasing intrauterine system (IUS)	●		
Medroxyprogesterone acetate depot	●		
sterilisation	●		
sexual intercourse with a vasectomised male partner only : vasectomy must be confirmed by negative semen analysis	●		
Ovulation inhibitory progesterone-only pill (desogestrel)	●		
Patient commits to complete and absolute abstinence	●		
negative pregnancy test before starting treatment	●		

not of childbearing potential

one of the following criteria have been met to determine patient is women NCBP

	Women of Childbearing Potential	Women of Non-Childbearing Potential*	Male
age ≥ 50 years and naturally amenorrhoeaic *** for≥ i years not induced by chemotherapy		●	
premature ovarian failure confirmed by specialist gynaecologist		●	
bilateral salpingo-oophorectomy, or hysterectomy		●	
XY genotype, tuner syndrome, uterine agenesisi		●	

* Refer to Healthcare Professional brochure for criteria to determine if patient is a woman of non-childbearing potential.
** Refer to Healthcare Professional brochure for information on contraception.
*** Amenorrhoea following cancer therapy or during breastfeeding does not rule out childbearing potential.

TREATMENT FOR A WOMAN OF CHILDBEARING POTENTIAL CANNOT START UNTIL PATIENT IS ESTABLISHED ON AT LEAST ONE EFFECTIVE METHOD OF CONTRACEPTION FOR AT LEAST 4 WEEKS PRIOR TO INITIATION OF THERAPY OR COMMITS TO ABSOLUTE AND CONTINUOUS ABSTINENCE AND PREGNANCY TEST IS NEGATIVE.

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