

Combined Checklist For Commencing Lenalidomide Treatment

This checklist will help you advise patients before they start treatment with Lenalidomide to ensure safe and proper use of the medicine. Please select the appropriate column for the patient risk category and refer to the counselling messages provided.

Counselling: Have you informed your patient or checked:	Male patients	Women of non-childbearing potential*	Women of childbearing potential
on the expected risk of teratogenic effects in the unborn child?			
on the need for reliable contraception** at least 4 weeks before the start of the treatment, throughout the duration of treatment, including dose interruptions, and for at least 4 weeks after the end of treatment or about the need for complete and uninterrupted sexual abstinence?	not required	not required	
that even in case of amenorrhea, the advice on contraception** should be followed?	not required	not required	
that the patient is capable of complying with contraceptive measures?		not required	
which are the reliable contraceptive methods** female patient or female partner of a male patient can use?		not required	
on the expected consequences of pregnancy and the urgency of immediate counselling if there is a possibility of pregnancy?		not required	
on the need to discontinue treatment immediately if female patient suspects they are pregnant?	not required	not required	
that if the female partner becomes pregnant while the male patient is taking lenalidomide or soon after treatment with lenalidomide has been stopped, the prescribing doctor should be informed and that it is recommended to refer the female partner to a physician specialised or experienced in teratology for evaluation and advice		not required	not required
about the need to use condoms throughout the course of treatment, during dose interruptions and for at least 7 days after the end of treatment, even if the patient had vasectomy, as semen may still contain lenalidomide, even if there is no sperm present, if female partner is pregnant or of childbearing potential and does not use reliable contraception methods?***		not required	not required
that during treatment, during dose interruptions and for at least 7 days after stopping the treatment the patients should not donate semen or sperm?		not required	not required
on risks and emergency precautions related to the use of lenalidomide?			
that the medicine should not be given to others and unused capsules should be returned to the dispensing pharmacist?			
about the thromboembolic risk and possible requirement to take thromboprophylaxis during treatment with lenalidomide			
that the patient should not donate blood while taking lenalidomide, during dose interruptions and for at least 7 days after stopping the treatment?			
your patient agrees to take pregnancy test in at least 4-weekly intervals, except in the case of confirmed tubal sterilisation?	not required	not required	
the patient had a negative pregnancy test before onset of treatment, even if she is completely and continuously sexually abstinent?	not required	not required	

*to determine whether female is of non-childbearing potential, see Information in Healthcare Professionals Guide

**for information regarding contraception see Information in Healthcare Professionals Guide

Contraceptive referral	Male patients	Women of non-childbearing Potential*	Women of childbearing potential
Contraceptive referral required	not required	not required	
Contraceptive referral made	not required	not required	
Contraceptive consultation completed	not required	not required	

Contraception Patient is currently established on one of the following for at least 4 weeks	Male patients	Women of non-childbearing Potential*	Women of childbearing potential
Implant	not required	not required	
Levonorgestrel-releasing intrauterine system (IUS)	not required	not required	
Medroxyprogesterone acetate depot	not required	not required	
Tubal Sterilisation (female sterilisation)	not required	not required	
Sexual intercourse with a vasectomised male partner only; vasectomy must be confirmed by two negative semen analyses	not required	not required	
Ovulation inhibitory progesterone-only pills (i.e., desogestrel) (progestogen-only pill that prevents release of an egg from the ovaries)	not required	not required	
Patient commits to complete and absolute abstinence	not required	not required	
Negative pregnancy test before starting treatment	not required	not required	

Not of childbearing potential One of the following criteria have been met to determine if the woman is of non-childbearing potential	Male patients	Women of non-childbearing Potential*	Women of childbearing potential
Age ≥ 50 years and naturally amenorrhoeic***for ≥ 1 year not induced by chemotherapy	not required		not required
Premature ovarian failure confirmed by a specialist gynaecologist	not required		not required
Bilateral salpingo-oophorectomy	not required		not required
XY genotype, Turner syndrome or uterine agenesis	not required		not required

***Amenorrhoea following cancer therapy or during breast-feeding 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 OR COMMITS TO COMPLETE AND CONTINUED ABSTINENCE AND PREGNANCY TEST IS NEGATIVE.