Zelvina® (Lenalidomide) Information for Healthcare Professionals

Checklist

Approved by the Malta Medicines Authority on the 02nd of February 2024.

Checklist for commencing Lenalidomide treatment in Women of Childbearing Potential

Patient Name **Date of Birth**

Counselling

	Insert √ or N/A
Inform of expected teratogenic risk to the unborn child	
Inform of the need for effective contraception 4 weeks before starting treatment, during treatment interruption, throughout the entire duration of treatment and for 4 weeks after the end of treatment or commit to absolute and continued abstinence	
Inform that that even if she has amenorrhea she must comply with advice on contraception	
Confirm patient is capable of complying with contraceptive measures	
Inform of the expected consequences of pregnancy and the need to stop treatment and consult rapidly if there is a risk of pregnancy	
Confirm patient agrees to undergo pregnancy testing at 4 weekly intervals unless confirmed tubal sterilisation	
Inform of hazards and necessary precautions associated with use of lenalidomide	
Inform patient not to share medication	
Inform to return unused capsules to pharmacist	
Inform not to donate blood whilst taking lenalidomide or for one week after stopping	
Inform about the thromboembolic risk and possible requirement to take thromboprophylaxis during treatment with lenalidomide	

Contraceptive referral

Contraceptive referral required	
Contraceptive referral made	
Contraceptive consultation completed	

Contraception

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

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 pill (i.e. desogestrel)	

Abstinence

Patient commits to complete and absolute abstinence	

Pregnancy test

Negative pregnancy test before starting treatment even if absolute and continued abstinence	

TREATMENT CANNOT START UNTIL PATIENT IS ESTABLISHED ON EFFECTIVE METHOD OF CONTRACEPTION FOR 4 WEEKS OR COMMITS TO COMPLETE AND CONTINUED ABSTINENCE AND PREGNANCY TEST IS NEGATIVE

REPORTING OF ADVERSE REACTIONS

Suspected adverse reactions and medication errors should be reported either to:

ADR Reporting, The Medicines Authority, Post-Licensing Directorate,
Sir Temi Zammit Buildings, Malta Life Sciences Park,
San Gwann SGN 3000, Malta
Website: www.medicinesauthority.gov.mt
e-mail: postlicensing.medicinesauthority@gov.mt

OR

Adalvo Limited
Malta Life Sciences Park,
Sir Temi Zammit,
Building 1, Level 4,
San Gwann Industrial Estate,
San Gwann, SGN 3000,
Malta
Email: pharmacovigilance@adalvo.com
Tel: +0040 727251514

Marketing Authorisation Holder
Adalvo Limited

Checklist for commencing Lenalidomide treatment in Women NOT of Childbearing Potential

Patient Name **Date of Birth**

Counselling

	Insert √ or N/A
Inform of expected teratogenic risk to the unborn child	
Inform patient not to share medication	
Inform to return unused capsules to pharmacist	
Inform not to donate blood whilst taking lenalidomide or for one week after stopping	
Inform of hazards and necessary precautions associated with use of lenalidomide	
Inform about the thromboembolic risk and possible requirement to take thromboprophylaxis during treatment with lenalidomide	

The following criteria have been met to determine patient is woman NOT of childbearing potential.

Age≥ 50 years and naturally amenorrhoeic* for ≥ 1 year not induced by chemotherapy	
Premature ovarian failure confirmed by specialist gynaecologist	
Bilateral salpingo-oophorectomy or hysterectomy	
XY genotype, Turner's syndrome, uterine agenesis	

*Amenorrhoea following cancer therapy or during lactation does not rule out childbearing potential.

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Checklist for commencing Lenalidomide treatment in Men

Patient Name **Date of Birth**

Counselling

	Insert √ or N/A
Inform of expected teratogenic risk to the unborn child	
Inform of need to use condoms (even if he has had vasectomy) throughout treatment duration, during dose interruption, and for one week after cessation of treatment if partner is pregnant or of childbearing potential and is not using effective contraception.	
Inform patient not to share medication	
Inform to return unused capsules to pharmacist	
Inform not to donate blood whilst taking lenalidomide or for one week after stopping	
Inform of hazards and necessary precautions associated with use of lenalidomide	
Inform about the thromboembolic risk and possible requirement to take thromboprophylaxis during treatment with lenalidomide	
Inform about the effective contraceptive methods that the female partner of a male patient can use	
Inform that if his female partner becomes pregnant whilst he is taking lenalidomide or shortly after he has stopped taking lenalidomide, he should inform his treating physician immediately and that it is recommended to refer the female partner to a physician specialised or experienced in teratology for evaluation and advice.	

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