Combined checklist for commencing Thalidomide treatment - UK

This checklist is to assist you with counselling a patient before they commence thalidomide 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 CBP	Women NCBP	Male
Inform of expected teratogenic risk to the unborn child	●	●	●
Inform of the need for effective contraception at least 4 weeks before starting treatment, during treatment interruption, throughout the entire duration of treatment 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 on contraception	●		
Inform of the requirement to discuss with the prescriber prescribing Thalidomide and the contraception method if the patient needs to change or stop their method of 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	●		
Inform that if his female partner becomes pregnant whilst he is taking thalidomide or shortly after he has stopped taking thalidomide, 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			●
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 Thalidomide	●	●	●
Inform patient not to share medication	●	●	●
Inform to return unused capsules to pharmacist	●	●	●
Inform not to donate blood whilst taking Thalidomide (including during dose interruptions) or for at least 7 days after stopping	●	●	●
Inform not to donate semen or sperm whilst taking Thalidomide (including during dose interruptions) or for at least 7 days after stopping			●
Inform of need to use condoms throughout treatment duration, during dose interruption, and for at least 7 days after cessation of treatment if partner is pregnant or of childbearing potential and not using effective contraception			●
Inform of requirement to provide a copy of the Treatment Initiation Form (TIF) to the pharmacy prior to the dispensing of the first prescription	●	●	●

Contraceptive referral	Women CBP	Women NCBP	Male
Contraceptive referral required	●		
Contraceptive referral made	●		
Contraceptive consultation completed	●		

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Contraception

Patient is currently established on one of the following for at least 4 weeks	Women CBP	Women NCBP	Male
Implant	●		
Levonorgestrel-releasing intrauterine system (IUS)	●		
Medroxyprogesterone acetate depot	●		
Tubal 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 confirmed on a monthly basis	●		
Negative pregnancy test before starting treatment	●		

Not of childbearing potential

One of the following criteria have been met to determine patient is woman NCBP	Women CBP	Women NCBP	Male
Age - ≥ 50 years and naturally amenorrheic for ≥ 1 year not induced by chemotherapy		●	
Premature ovarian failure confirmed by specialist gynaecologist		●	
Bilateral salpingo-oophorectomy		●	
XY genotype, Turner's syndrome, uterine agenesis		●	

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 COMPLETE AND CONTINUED ABSTINENCE AND PREGNANCY TEST IS NEGATIVE.

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Pharmacy registration and dispensing of Thalidomide – UK