

Revlimid[®] Treatment Initiation Form

Women Not of Childbearing Potential

This Treatment Initiation Form must be completed for each female patient not of childbearing potential prior to the initiation of their Revlimid treatment. **The form should be retained with their medical records, and a copy provided to the patient.**

The aim of the Treatment Initiation Form is to assist both prescribers and patients to ensure all necessary steps are taken to prevent foetal exposure to lenalidomide and to assist in ensuring that patients are fully informed of and understand the risk of teratogenicity and other adverse effects associated with the use of lenalidomide. It is not a contract and does not absolve anybody from his/her responsibilities with regard to the safe use of the product and prevention of foetal exposure.

Patient Name

Date of Birth

Counselling

| | Insert \checkmark 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 Revlimid or for one week after stopping | |
| Inform of hazards and necessary precautions associated with use of Revlimid | |
| Inform about the thromboembolic risk and possible requirement to take thromboprophylaxis during treatment with Revlimid | |

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

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

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

I have fully explained to the patient named above the nature, purpose and risks of the treatment associated with Revlimid, especially the risks to women of childbearing potential. I will comply with all my obligations and responsibilities as the prescribing physician of Revlimid.

Physician Name

Physician Signature

Date

Patient Name

Date of Birth

Patient: please read thoroughly and initial the adjacent box if you agree with the statement

| | |
|---|-----------------------------|
| My doctor has explained to me and I have understood the possible risks and the possible benefits associated with Revlimid® (lenalidomide). I have had the opportunity to ask questions and I have understood the answers provided to those questions. | <i>Patient initials</i> |
| I have received, read and understood the Patient Information Brochure | <i>Patient initials</i> |
| I understand that Revlimid® (lenalidomide) has been prescribed for me personally and that I should not share it with any other person even if they have the same condition as me. I should store Revlimid® (lenalidomide) out of the reach of children. | <i>Patient initials</i> |
| I will return any unused capsules for my pharmacist. | <i>Patient initials</i> |
| I will not donate blood during treatment or for one week after stopping treatment | <i>Patient initials</i> |

Patient Confirmation

I confirm that I understand and will comply with the requirements of the Revlimid Pregnancy Prevention Programme, and I agree that my doctor can initiate my treatment with Revlimid

Patient Signature

Date