

Revlimid®

Patient Brochure

Brochure for Women Patients of Childbearing Potential

- **Revlimid is expected to be harmful to the unborn child.**
- **Revlimid has been shown to produce birth defects in animals and it is expected to have a similar effect in humans**
- In order to ensure that an unborn baby is not exposed to Revlimid, your doctor will complete a Patient Card documenting that you have been informed of the requirement for you NOT to become pregnant during treatment with Revlimid and for one month after finishing Revlimid.
- You should never share Revlimid with anyone else
- You should always return any unused capsules to the pharmacist
- You should not donate blood during treatment or for one week after treatment finishes
- The most common, serious side effects of Revlimid are a reduction in the number of blood cells that fight infection and also the blood cells which help the blood to clot. For this reason your doctor will arrange for you to have blood tests weekly for at least the first 8 weeks of treatment. Revlimid may also cause thromboembolic events (blood clots in the veins and arteries). Therefore you must tell your doctor immediately if you experience:
 - any fever, chills, sore throat, cough, mouth ulcers or any other symptoms of infection
 - any bleeding or bruising in the absence of injury
 - any chest or leg pain
 - any shortness of breath.If you have any risk factors for developing thromboembolic events, e.g. smoking, high blood pressure, high cholesterol, a clotting disorder, a previous blood clot (in a vein or artery), you should tell your doctor.
- If you experience any side effects whilst taking Revlimid you should tell your doctor

Pregnancy Prevention Programme

- You should tell your doctor if you are pregnant or think you may be pregnant or are planning to become pregnant, as **Revlimid is expected to be harmful to an unborn child**
- If you are able to become pregnant, you must follow all the necessary measures to prevent you becoming pregnant and ensuring you are not pregnant during treatment. Before starting the treatment, you should ask your doctor if you are able to become pregnant, even if you think this is unlikely.

- If you are able to become pregnant and even if you agree and confirm every month that you will not engage in sexual activity you will have pregnancy tests under the supervision of your doctor before treatment. These will be repeated every 4 weeks during treatment and 4 weeks after the treatment has finished unless it is confirmed that you have had a tubal sterilisation)
- If you are able to become pregnant you must use effective methods of contraception for 4 weeks before starting treatment, during treatment, and until 4 weeks after stopping treatment. Your doctor will advise you on appropriate methods of contraception as some types of contraception are not recommended with Revlimid. It is essential therefore that you discuss this with your doctor
- Where to get advice on contraception (*Add locally according to local practice and arrangements*)
- If you suspect you are pregnant at any time whilst taking Revlimid or in the 4 weeks after stopping, you must stop Revlimid immediately and immediately inform your doctor.
- Local specific arrangements on the details that a study is being conducted to collect information regarding the safety of the drug and to monitor its appropriate use; and that MDS patients should be included in the study prior to the start of the treatment with Revlimid.

Brochure for Women Patients Not of Childbearing Potential

- **Revlimid is expected to be harmful to the unborn child.**
- **Revlimid has been shown to produce birth defects in animals and it is expected to have a similar effect in humans**
- In order to ensure that an unborn baby is not exposed to Revlimid, you doctor will complete a Patient Card documenting that you are not able to become pregnant
- You should never share Revlimid with anyone else
- You should always return any unused capsules to the pharmacist
- You should not donate blood during treatment or for one week after treatment finishes
- The most common, serious side effects of Revlimid are a reduction in the number of blood cells that fight infection and also the blood cells which help the blood to clot. For this reason your doctor will arrange for you to have blood tests weekly for at least the first 8 weeks of treatment. Revlimid may also cause thromboembolic events (blood clots in the veins and arteries). Therefore you must tell your doctor immediately if you experience:
 - any fever, chills, sore throat, cough, mouth ulcers or any other symptoms of infection
 - any bleeding or bruising in the absence of injury
 - any chest or leg pain
 - any shortness of breath.If you have any risk factors for developing thromboembolic events, e.g. smoking, high blood pressure, high cholesterol, a clotting disorder, a previous blood clot (in a vein or artery), you should tell your doctor.
- If you experience any side effects whilst taking Revlimid you should tell your doctor
- Local specific arrangements on the details that a study is being conducted to collect information regarding the safety of the drug and to monitor its appropriate use; and that MDS patients should be included in the study prior to the start of the treatment with Revlimid.

Brochure for male patients

- **Revlimid may be harmful to the unborn child.**
- **Revlimid has been shown to produce birth defects in animals and it is expected to have a similar effect in humans**
- In order to ensure that an unborn baby is not exposed to Revlimid, you doctor will complete a Patient Card documenting that you have been informed of the requirement for your partner NOT to become pregnant during treatment with Revlimid and for one month after you finish Revlimid.
- You should never share Revlimid with anyone else
- You should always return any unused capsules to the pharmacist
- You should not donate blood during treatment or for one week after treatment finishes
- The most common, serious side effects of Revlimid are a reduction in the number of blood cells that fight infection and also the blood cells which help the blood to clot. For this reason your doctor will arrange for you to have blood tests weekly for at least the first 8 weeks of treatment. Revlimid may also cause thromboembolic events (blood clots in the veins and arteries). Therefore you must tell your doctor immediately if you experience:
 - any fever, chills, sore throat, cough, mouth ulcers or any other symptoms of infection
 - any bleeding or bruising in the absence of injury
 - any chest or leg pain
 - any shortness of breath.If you have any risk factors for developing thromboembolic events, e.g. smoking, high blood pressure, high cholesterol, a clotting disorder, a previous blood clot (in a vein or artery), you should tell your doctor.
- If you experience any side effects whilst taking Revlimid you should tell your doctor
- Revlimid passes into human semen. If your partner is pregnant or able to become pregnant, and she doesn't use effective contraception, you must use condoms, during treatment, during dose interruptions and 1 week after the end of treatment even if you have had a vasectomy.
- If your partner does become pregnant whilst you are taking Revlimid, you should inform your treating doctor immediately and your partner should also consult her doctor immediately.

- Local specific arrangements on the details that a study is being conducted to collect information regarding the safety of the drug and to monitor its appropriate use; and that MDS patients should be included in the study prior to the start of the treatment with Revlimid.