Brochure for Male Patients

Revlimid®

▼This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get.

- **Revlimid® is expected to be harmful to the unborn child.**

- **Revlimid® is the trade name for lenalidomide**

- Lenalidomide is structurally related to thalidomide, which is known to cause severe life-threatening birth defects. If thalidomide is taken during pregnancy it can cause severe birth defects or death to an unborn baby. In the 1950s and 1960s thalidomide was prescribed to pregnant women as a sedative and to relieve morning sickness. As a result approximately 12,000 children were born with severe birth defects caused by thalidomide. Birth defects may include shortened arms or legs, malformed hands or feet, eye or ear defects, and internal organ problems.

- **Lenalidomide has been shown to produce birth defects** (short limbs, bent fingers/toes, wrist and/or tail, extra or missing fingers/toes) **in animals and it is expected to have a similar effect in humans**

- Prior to treating you with Revlimid®, you will be asked to sign a Treatment Initiation Form to confirm that the benefits and risks of Revlimid® therapy have been explained to you and that you have understood and agree to comply with the requirements of the Risk Management Plan.

- 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 store Revlimid® out of the reach of children.

- You should always return any unused capsules to the pharmacist

- You should not donate blood during treatment or for 7 days after treatment finishes

Side-effects

Like all medicines, Revlimid® can cause side-effects, although not everybody gets them. Some are more common than others and some are more serious than others. These are not all the side-effects that have been reported with Revlimid®. Ask your doctor or pharmacist if you would like more information.

Almost all side-effects are temporary and can be easily prevented or treated. The most important thing is to be aware of what to expect and what to report to your doctor.

Serious side-effects and what to look out for:

Low white blood cells and platelets

Revlimid® may cause a drop in the number of white blood cells in your blood. This can make you more prone to infections. You may be prescribed treatments to prevent infections or to boost your blood counts.

Revlimid® may also cause a drop in the number of platelets in your blood. If the count drops too low you may be at risk of bleeding.

For this reason your doctor will arrange for you to have blood tests weekly for at least the first 8 weeks of treatment and at least every month after that.

Venous and Arterial Thromboembolism (Clots in blood vessels)

Revlimid® treatment may increase the risk of you developing blood clots in some blood vessels in the body. This is sometimes called deep vein thrombosis (DVT) or arterial thromboembolic events (ATEEs). People with myeloma may already have a higher risk of blood clots in vessels. You may be prescribed treatment to help prevent blood clots in vessels from forming.

You should contact your doctor immediately if you experience any of the following:

- any fever, chills, sore throat, cough, mouth ulcers or any other symptoms of infection [including within the bloodstream (sepsis)]
- 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.

Other common side-effects with Revlimid® are:

- Muscle cramps or weakness
- Diarrhoea
- Constipation
- Nausea (feeling sick)
- Tiredness
- Difficulty sleeping
- Changes in body weight

Peripheral neuropathy

Lenalidomide is structurally related to thalidomide, which is known to induce severe peripheral neuropathy (numbness, tingling, or pain in your hands and feet which may be due to nerve damage). At this time, the potential for nerve damage associated with long-term Revlimid® use cannot be ruled out.

Remember, almost all side-effects are temporary and can be easily prevented or treated. If you experience any side-effect that causes you concern, contact your doctor or hospital team.

- If you experience any side effects whilst taking Revlimid® you should tell your doctor or pharmacist.

- Revlimid® passes into human semen. Unless you abstain from heterosexual intercourse, 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 7 days after the end of treatment even if you have had a vasectomy.

Each pregnancy prevention method has a different level of effectiveness and mode of action, including in some cases, the prevention of foetal implantation in the womb. Their published success/failure rate is based on using them perfectly.

You, or your female partner, must talk to your doctor, fertility expert or your gynaecologist about which method is most appropriate for you.

- If your partner has been using effective contraception, she must continue doing so for at least 4 weeks

- If your partner does become pregnant whilst you are taking Revlimid or shortly after you have stopped taking Revlimid, you should inform your treating doctor immediately and your partner should also consult her doctor immediately.

Further Information
Further information regarding your Revlimid treatment for multiple myeloma can be obtained from the following organisations:

- International Myeloma Foundation **www.myeloma.org**
- Myeloma Euronet **www.myeloma-euronet.org**
- Myeloma UK **www.myelomaonline.org.uk**

Revlimid European Public Assessment Report

- **http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/000717/human_med_001034.jsp&mid=WC0b01ac058001d124**

