Brochure for Women Patients Not of Childbearing Potential

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 are not able to become pregnant

- 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). There was no increase in peripheral neuropathy observed with long term use of lenalidomide for the treatment of newly diagnosed multiple myeloma.

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.

Reporting of Adverse Reactions
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in the package leaflet. You should also report side effects directly via the national reporting system to

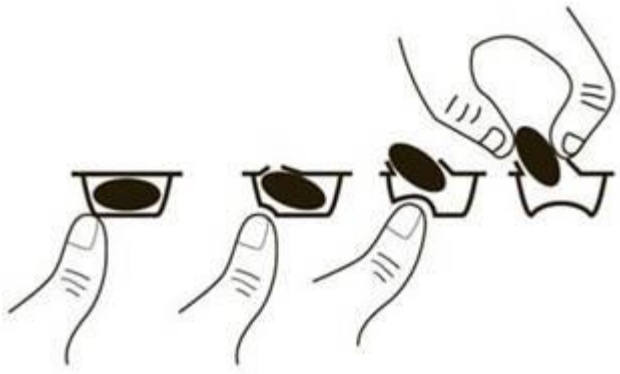
ADR Reporting, The Medicines Authority, Post-Licensing Directorate,
Sir Temi Zammit Buildings, Malta Life Sciences Park,
San Gwann SGN 3000, Malta
Website: www.medicinesauthority.gov.mt
e-mail: postlicensing.medicinesauthority@gov.mt
OR
ADR Reporting: www.medicinesauthority.gov.mt/adrportal

By reporting side effects you can help provide more information on the safety of this medicine.

Points to consider for handling the medicinal product: for patients, family members and caregivers

Keep the blisters with the capsules in the original pack.

Capsules can occasionally become damaged when pressing them out of the blister, especially when the pressure is put onto the middle of the capsule. Capsules should not be pressed out of the blister by putting pressure on the middle nor by putting pressure on both ends as this can result in deformation and breaking of the capsule.
It is recommended to press only on one site at the end of the capsule (see figure below) as therefore the pressure is located to one site only which reduces the risk of capsule deformation or breakage.



When handling the medicinal product use the following precautions to prevent potential exposure if you are a family member and/or caregiver

- Wear disposable gloves when handling product and or packaging (i.e., blister or capsule).
- Use proper technique when removing gloves to prevent potential skin exposure (see below).
- Place gloves in sealable plastic polyethylene bag and dispose according to local requirements.
- Wash hands thoroughly with soap and water after removing gloves

If a drug product package appears visibly damaged, use the following extra precautions to prevent exposure

- If outer carton is visibly damaged – **Do Not Open**
- If blister strips are damaged or leaking or capsules are noted to be damaged or leaking – **Close Outer Carton Immediately**
- Place the product inside a sealable plastic polyethylene bag
- Return unused pack to the pharmacist for safe disposal as soon as possible

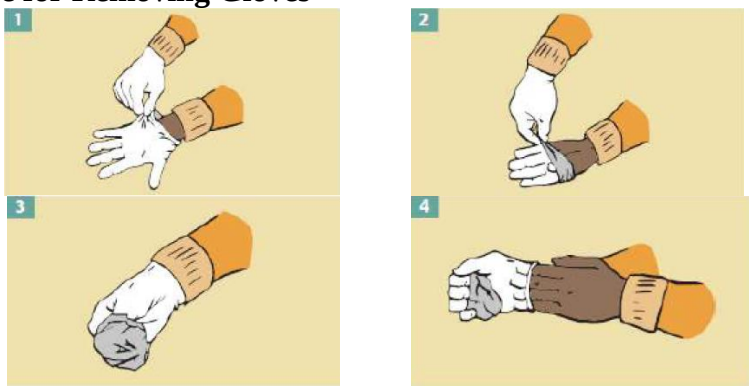
If product is released or spilled, take proper precautions to minimize exposure by using appropriate personal protection

- If capsules are crushed or broken, dust containing drug substance may be released. Avoid dispersing the powder and avoid breathing the powder.
- Wear disposable gloves to clean up the powder.
- Place a damp cloth or towel over the powder area to minimize entry of powder into the air. Add excess liquid to allow the material to enter solution. After handling clean the area thoroughly with soap and water and dry it.
- Place all contaminated materials including damp cloth or towel and the gloves into a sealable polyethylene plastic bag and dispose in accordance to local requirements for medicinal products.
- Wash your hands thoroughly with soap and water after removing the gloves.
- Please report to the prescribing physician and/or pharmacist immediately.

If the contents of the capsule are attached to the skin or mucous membranes

- If you touch the drug powder, please wash exposed area thoroughly with running water and soap.
- If your eye had contact with the powder, if worn and if easy to do, remove contact lenses and discard them. Immediately flush eyes with copious quantities of water for at least 15 minutes. If irritation occurs please contact an ophthalmologist.

Proper Technique for Removing Gloves



- Grasp outside edge near wrist (1).
- Peel away from hand, turning glove inside-out (2).
- Hold in opposite gloved hand (3).
- Slide ungloved finger under the wrist of the remaining glove, be careful not to touch the outside of the glove (4).
- Peel off from inside, creating a bag for both gloves.
- Discard in appropriate container.
- Wash your hands with soap and water thoroughly

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**

