Revlimid® (lenalidomide)

Guide for Male Patients

▼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.

Summary

- Revlimid® is the trade name for lenalidomide
- Lenalidomide is expected to be harmful to the unborn child.
- Lenalidomide has been shown to produce birth defects in animals and it is expected to have a similar effect in humans.
- Prior to treating you with lenalidomide, 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. Kindly review carefully the Package leaflet: Information for the patient, supplied with each Revlimid pack.
- In order to ensure that an unborn baby is not exposed to lenalidomide, you prescriber will complete a Patient Card documenting that you have been informed of the requirement for your partner NOT to become pregnant throughout the treatment with lenalidomide and for 7 days after you stop lenalidomide.
- You should never share lenalidomide with anyone else.
- You should always return any unused capsules to the pharmacist for safe disposal as soon as possible.
- If you experience any side effects whilst taking lenalidomide you should tell your prescriber or pharmacist.
- Lenalidomide 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, throughout the duration of your treatment, during dose interruptions and 7 days after you stop lenalidomide even if you have had a vasectomy.
- If your partner does become pregnant whilst you are taking lenalidomide or within 7 days after you have stopped taking lenalidomide, you should inform your prescriber immediately and your partner should also consult her doctor immediately.
- You should not donate blood or semen or sperm during treatment, during dose interruptions, or for 7 days after stopping treatment.
- For additional information, please refer to the Package Leaflet.

Side Effects

Like all medicines, lenalidomide can cause side-effects, although not everybody gets them. Some side effects are more common than others and some are more serious than

others. Ask your prescriber or pharmacist if you would like more information and refer to the Package Leaflet. Almost all side effects are temporary and can be easily prevented and treated. The most important thing is to be aware of what to expect and what to report to your prescriber. It is important that you talk to your prescriber if you have any side effects during lenalidomide treatment.

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

AND

AM Mangion Ltd
Mangion House
New Street off Valletta Road
Luqa LQA6000, Malta
Email: pv@ammangion.com
Tel – 00 356 23976333

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

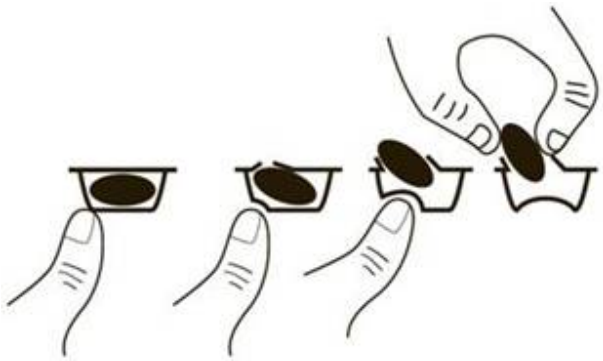
POINTS TO CONSIDER FOR HANDLING THE MEDICINAL PRODUCT: FOR PATIENTS, FAMILY MEMBERS AND CAREGIVERS

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.

Healthcare professionals, caregivers and family members should wear disposable gloves when handling the blister or capsule. Gloves should then be removed carefully to prevent skin exposure, placed in a sealable plastic polyethylene bag and disposed of in accordance with local requirements. Hands should then be washed thoroughly with soap and water. Women who are pregnant or suspect they may be pregnant should not handle the blister or capsule. Refer below for further guidance.



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

- If you are a woman who is pregnant or suspect that you may be pregnant, you should not handle the blister or capsule.
- 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

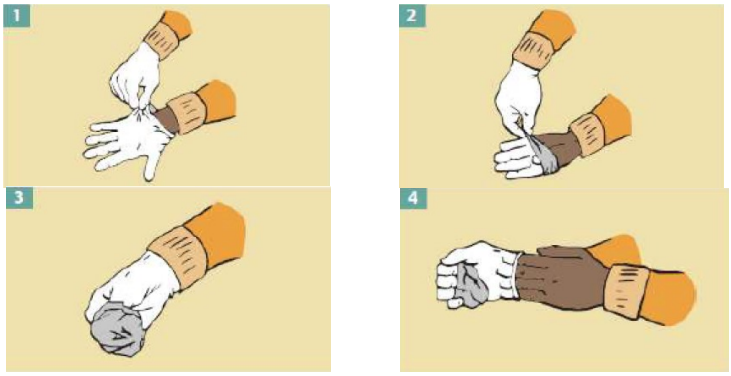
requirements for medicinal products.

- Wash your hands thoroughly with soap and water after removing the gloves.
- Please report to the prescriber 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**

This Material is a condition to the Marketing Authorization, and it has been approved by the Medicines Authority on [25/02/2021]

Marketing Authorisation Holder
Bristol-Myers Squibb Pharma EEIG