Revlimid® (lenalidomide)

Guide for Women Patients of Childbearing Potential

▼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. Foetal exposure must be avoided.

- Prior to treating you with lenalidomide, you will be asked to sign a Treatment Initiation Form to confirm that the benefits and risks of lenalidomide 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 **l**enalidomide, you doctor will complete a Patient Card documenting that you have been informed of the requirement for you NOT to become pregnant throughout the duration of your treatment with lenalidomide and for at least 4 weeks after stopping 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.

- You should not donate blood during treatment during dose interruptions, or for 7 days after stopping treatment.
- For additional information, please refer to the Package Leaflet.
- You must never take lenalidomide if:
    - You are pregnant
    - You are a woman who is able to become pregnant, even if you are not planning to become pregnant, unless all of the conditions of the Pregnancy Prevention Programme are met.

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. These are not all the side-effects that have been reported with lenalidomide. 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 or 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.

Pregnancy Prevention Programme

- You should tell your prescriber if you are pregnant or think you may be pregnant or are planning to become pregnant, as **lenalidomide 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 prescriber 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 heterosexual sexual activity, you will have pregnancy tests under the supervision of your doctor before treatment. These will be repeated at least every 4 weeks during treatment and at least 4 weeks after the treatment has finished (unless it is confirmed that you have had a tubal sterilisation).

- The date and result of the monthly pregnancy test will be documented on the Patient Card. Your pharmacist will check the Patient Card prior to each dispensing of lenalidomide.

- If you are able to become pregnant you must use effective methods of contraception for at least 4 weeks before starting treatment, throughout the duration of the treatment (including dose interruptions), and for at least 4 weeks after stopping treatment. Your prescriber will advise you on appropriate methods of contraception as some types of contraception are not recommended with lenalidomide. It is essential therefore that you discuss this with your prescriber.

- If you do not currently have effective contraception, you doctor will be able to advise you where you can obtain this.

- The following can be considered to be examples of effective methods of contraception:
  - Implant (hormonal pregnancy prevention methods implanted under the skin)
  - Levonorgestrel-releasing intrauterine system (IUS) (hormone releasing pregnancy prevention coil placed in the uterus)
  - Medroxyprogesterone acetate depot (long acting pregnancy prevention hormonal injection)
  - Tubal Sterilisation (female sterilisation)
  - Sexual intercourse with a vasectomised male partner only; vasectomy must be confirmed by two negative semen analyses
  - Ovulation inhibitory progesterone-only pills (i.e. desogestrel) (progestogen-only pill that prevents release of an egg from the ovaries)

- If you suspect you are pregnant at any time whilst taking lenalidomide, or in the 4 weeks after stopping, you must stop lenalidomide immediately and immediately inform your prescriber. Your prescriber will refer you to a physician specialised or experienced in teratology for evaluation and advice.

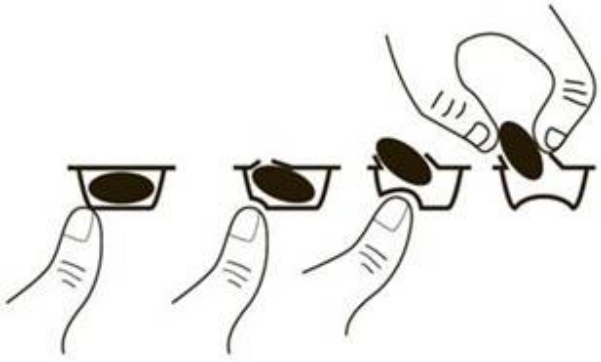
POINTS TO CONSIDER FOR HANDLING THE MEDICINAL PRODUCT: FOR PATIENTS, FAMILY MEMBERS AND CAREGIVERS

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

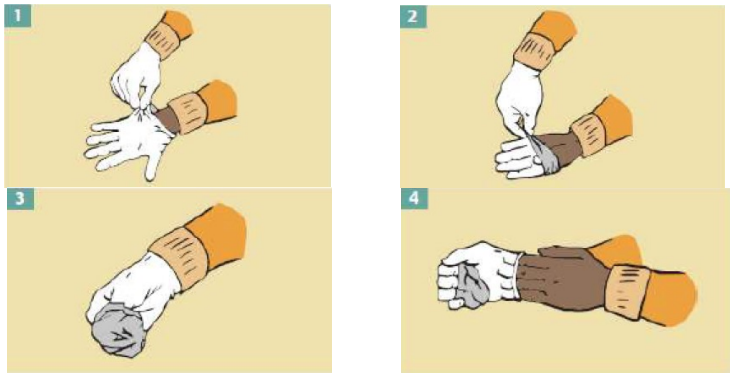
- If capsules are crushed or broken, dust containing drug substance may be released. Avoid dispersing the powder and avoid breathing the powder.
- Wear disposable gloves to clean up the powder.
- Place a damp cloth or towel over the powder area to minimize entry of powder into the air. Add excess liquid 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 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 lenalidomide 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