Zelvina® (Lenalidomide) Patient Brochure

Approved by the Malta Medicines Authority on the 02nd of February 2024.

Brochure for Women Patients of Childbearing Potential

- **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.**

- To ensure that an unborn baby is not exposed to Lenalidomide, 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 Lenalidomide and for one month after finishing Lenalidomide.

- You should never share Lenalidomide with anyone else.

- You should always return any unused capsules to the pharmacist.

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

- The most common, serious side effects of Lenalidomide 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 and at least every month after that. Lenalidomide 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 [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.

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

Pregnancy Prevention Programme

- You should tell your doctor if you are pregnant or think you may be pregnant or 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 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 Lenalidomide. It is essential therefore that you discuss this with your doctor.

- 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 doctor.

Brochure for Women Patients Not of Childbearing Potential

- **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.**
- To ensure that an unborn baby is not exposed to Lenalidomide, your doctor will complete a Patient Card documenting that you are not able to become pregnant.
- You should never share Lenalidomide with anyone else.
- You should always return any unused capsules to the pharmacist.
- You should not donate blood during treatment and for 7 days after treatment finishes.
- The most common, serious side effects of Lenalidomide 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 and at least every month after that. Lenalidomide 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 [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, eg., 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 Lenalidomide you should tell your doctor or pharmacist

Brochure for male patients

- **Lenalidomide may 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.**

- To ensure that an unborn baby is not exposed to Lenalidomide, your doctor will complete a Patient Card documenting that you have been informed of the requirements for your partner NOT to become pregnant during treatment with Lenalidomide and for 7 days after you finish Lenalidomide.

- You should never share Lenalidomide with anyone else.

- You should always return any unused capsules to the pharmacist.

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

- The most common, serious side effects of Lenalidomide 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 and at least every month after that. Lenalidomide 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 [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.

- If you experience any side effects whilst taking Lenalidomide you should tell your doctor 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, during treatment, during dose interruptions and 7 days after the end of treatment even if you have had a vasectomy.

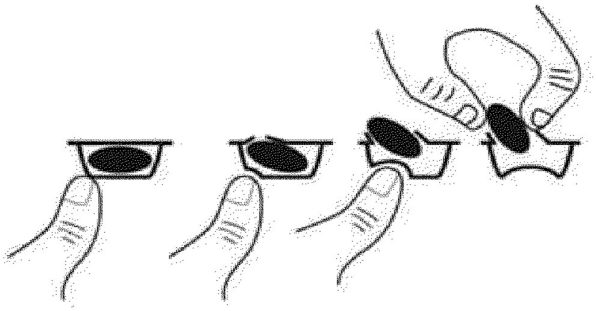
- If your partner does become pregnant whilst you are taking Lenalidomide or shortly after you have stopped taking Lenalidomide, you should inform your treating doctor immediately and your partner should also consult her doctor immediately.

Brochure Part for All patients

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 deformation and breaking of the capsule. It is recommended to press only on one side at the end of the capsule (see figure below) as therefore the pressure is located on one side 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

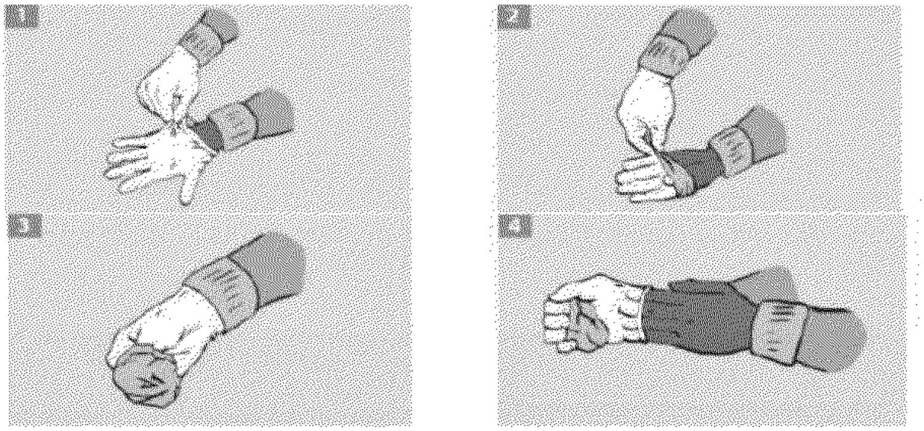
- If capsules are crushed or broken, dust containing drug substance may be released. Avoid dispersing the powder and avoid breathing the powder.
- Wear disposable gloves to clean up the powder.

- 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 gloves into a sealable polyethylene plastic bag and dispose in accordance with 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 membrane

- 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 immediately

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

REPORTING OF ADVERSE REACTIONS

Suspected adverse reactions and medication errors should be reported either 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

Adalvo Limited

Malta Life Sciences Park,

Sir Temi Zammit,

Building 1, Level 4,

San Gwann Industrial Estate,

San Gwann, SGN 3000,

Malta

Email: pharmacovigilance@adalvo.com

Tel: +0040 727251514

Marketing Authorisation Holder

Adalvo Limited