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## **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**
- In order to ensure that an unborn baby is not exposed to lenalidomide, your doctor will complete an acknowledgement 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 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.

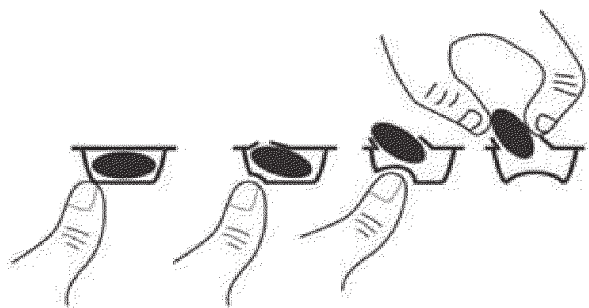
- If you experience any side effects whilst taking lenalidomide you should tell your doctor or pharmacist

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## 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 (ie., 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

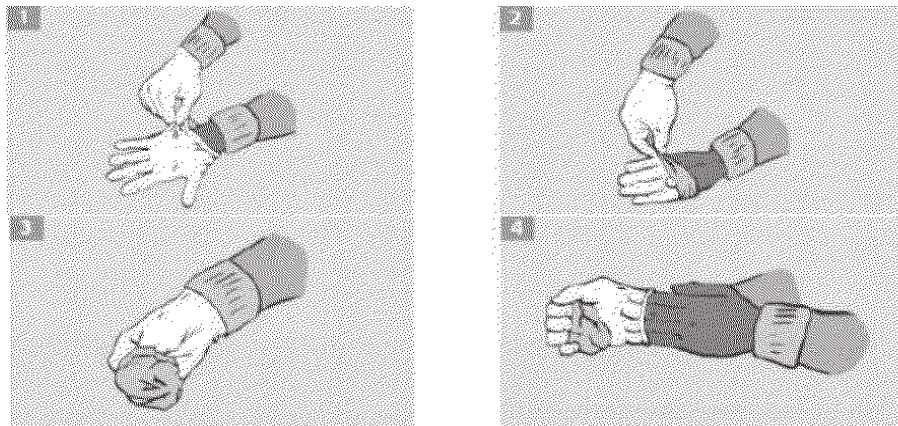
- If capsules are crushed or broken, dust containing drug substance may be released. Avoid dispersing the powder and avoid breathing the powder
- Wear disposable gloves to clean up the powder

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- 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 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 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 effects you may get.

#### **Reporting of Adverse Reactions**

To report Adverse Reactions please email [adverse.event@tearaiobiofarma.com](mailto:adverse.event@tearaiobiofarma.com) or contact us at [lenalidomide.co.nz](http://lenalidomide.co.nz) for further details.