

# **IMNOVID® (POMALIDOMIDE)**

## **PREGNANCY PREVENTION PROGRAM**

### **PRODUCT HANDLING INSTRUCTIONS FOR IMMUNOMODULATORY AGENTS**

Medicines Authority Approval Date: *18 October 2023*

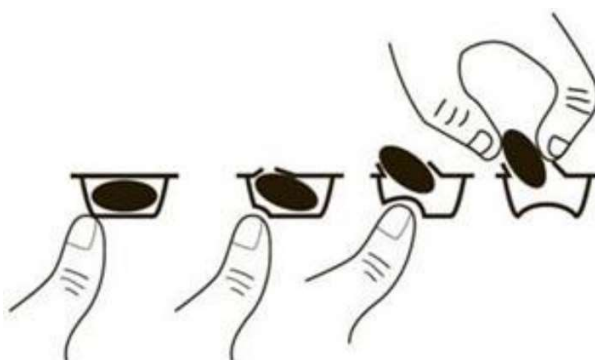
## Points to consider for handling the medicinal product: for healthcare professionals, family members and caregivers

Do not share the medicinal product with anyone else, even if they have similar symptoms. Store them safely so that no-one else can take them by accident and keep them out of the reach of children.

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. The pressure should be located at one site only, which reduces the risk of the capsule deforming or breaking (see figure below).

Healthcare professionals, family members, and caregivers should wear disposable gloves when handling the blister or capsule. Remove gloves carefully to prevent skin exposure. Place in a sealable plastic polyethylene bag. Dispose of any unused medication in accordance with local regulations. 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 healthcare professional, 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 (ie, blister or capsule).
- Use proper technique when removing gloves to prevent potential skin exposure (see below).
- Place gloves in a sealable plastic polyethylene bag and dispose them according to local requirements.
- Wash hands thoroughly with soap and water after removing gloves.
- Patients should be advised never to give pomalidomide to another person.

**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.

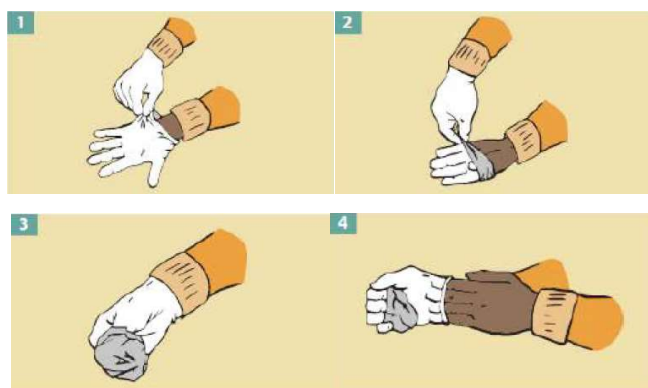
**If product is released or spilled, take proper precautions to minimize exposure by using appropriate personal protection**

- If capsules are crushed or broken, dust containing drug substance may be released. Avoid dispersing the powder and avoid breathing on or inhaling 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, then dry it.
- Place all contaminated materials including damp cloth or towel and the gloves into a sealable polyethylene plastic bag. Dispose of it according 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, being 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.

## REPORTING OF ADVERSE REACTIONS

The safe use of pomalidomide is of paramount importance. As part of BMS's ongoing safety monitoring, the company wishes to learn of Adverse Reactions that have occurred during the use of pomalidomide. Please contact AM Mangion Ltd immediately on Tel No 00356 23976333 and email [pv@ammangion](mailto:pv@ammangion).

Suspected Adverse Drug Reactions (side effects) or medication errors may be reported using the Medicines Authority ADR reporting form, which is available online at <http://www.medicinesauthority.gov.mt/adrportal>, and sent by post or email to;

**P:** Pharmacovigilance Section at Post-Licensing Directorate, Medicines Authority, Sir Temi Żammit Buildings, Malta Life Sciences Park, San Ġwann SĠN 3000

**E:** [postlicensing.medicinesauthority@gov.mt](mailto:postlicensing.medicinesauthority@gov.mt)

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