Patient Manual

PREGNANCY PREVENTION PROGRAM (PPP)

version 1.2

MYOLID® (LENALIDOMIDE)

To report any undesirable effects encountered while taking this medicine please consult your doctor

Important warnings associated with the use of LENALIDOMIDE.

The prescription and subsequent dispensing of lenalidomide must take place through a Risk Minimisation Plan under the Pregnancy Prevention Program (PPP) due to the risk of harm to an unborn child. Your doctor will have a system at his disposal, which will allow him, after having studied your case, to carry out an appropriate prescription and a safe dispensing.

In this manual you will find all the measures to be taken for the safe use of lenalidomide. It is therefore recommended to consult it carefully before starting the therapy.

The manual provides information for each of the three (3) patient risk categories: women of childbearing potential, women of no childbearing potential, and men.

Side effects

Like all medicines, lenalidomide can cause side effects, although not everyone gets them. Some side effects may be more common and others more serious. Before starting treatment with lenalidomide, your doctor will explain the possible side effects and advise you on what to do, in relation to their type and severity. Most side effects are temporary and can be easily prevented or treated. It is important that you know what to expect and what to report to your doctor. It is important that you report any side effects that you will experience during lenalidomide therapy to your doctor.

SPECIAL WARNINGS FOR ALL PATIENTS

Lenalidomide may impair foetal development.

Lenalidomide causes birth defects in animals and a similar effect is expected in humans.

Tell your doctor immediately if you experience side effects during treatment with lenalidomide.

Do NOT donate blood during treatment and for at least 7 days after stopping lenalidomide treatment. Transfusion of blood to pregnant or potentially fertile women could expose the foetus to risks of congenital malformations (birth defects).

HOW TO STORE AND HANDLE LENALIDOMIDE

Use lenalidomide only as directed by your doctor.
Store lenalidomide at room temperature (at or below 30°C and out of the sight and reach of children).

Do not take the medicine beyond the expiry date which is printed on the carton. Do not use this medicine if you notice any packaging that is damaged or has signs of tampering.

The capsules should be taken whole: do not divide, chew, or open the capsules.

Return the unused medicine to your doctor or pharmacist for proper disposal.

Lenalidomide should only be taken by you. DO NOT SHARE IT WITH ANYONE, not even with those who show symptoms identical to yours. Accidental or inappropriate intake by pregnant or potentially fertile women could cause birth defects and other serious problems to the foetus.

Pregnancy Prevention Program

Lenalidomide can impair foetal development.

Lenalidomide is structurally related to thalidomide, an active substance known to cause human teratogenicity, causing severe life-threatening birth defects. In fact, lenalidomide induced malformations similar to those described for thalidomide in monkeys. In humans, a teratogenic effect of lenalidomide, if taken during pregnancy, is expected.

Lenalidomide must not be taken:

- **if you are pregnant**
- **if you are breastfeeding**
- **if you are able to become pregnant, even if you do not intend to become pregnant, unless all conditions of the Pregnancy Prevention Program, outlined in this manual, are met.**

Special warnings for women of childbearing potential

You must inform your doctor if you are, think you may be pregnant or plan to become pregnant as lenalidomide may be harmful to an unborn baby.

If you are a woman of childbearing potential, it is important that you take all necessary precautions to avoid becoming pregnant and to be sure that you are not pregnant during treatment. Before starting treatment, you should ask your doctor if you are able to become pregnant, even if you think this is unlikely.

To avoid foetal exposure to lenalidomide, your prescriber will complete the Pregnancy Prevention Program Checklist to document that you have been advised to AVOID pregnancy while on lenalidomide treatment and for at least 4 weeks after stopping treatment.

Before starting treatment, your doctor will conduct a pregnancy test to check that you are not pregnant.

Once your doctor has confirmed the negative result of your test, you will need to use at least one effective method of contraception unless you are committed to observing absolute and continuous sexual abstinence, confirmed by a pregnancy test.

Your doctor will advise you on the suitable contraceptive methods and on the need to follow the contraceptive method precisely, punctually and continuously.

Contraception must be started at least 4 weeks before treatment, continued during treatment, including dose interruptions, and for at least 4 weeks after treatment has ended.

Unless you have had tubal sterilisation and this has been documented, you will have to undergo a pregnancy test, under the supervision of your doctor at least every 4 weeks during therapy, during any dose interruptions and at least 4 weeks after the treatment has ended, even if you confirm absolute and continuous sexual abstinence.

If, despite these careful methods of pregnancy prevention, you become pregnant while taking lenalidomide or in the 4 weeks following the end of treatment you must immediately stop treatment and inform your doctor, who will refer you to a specialist doctor or doctor with experience in teratology for advice and evaluation.

Special warnings for women of non-childbearing potential

Before starting treatment, your doctor will complete the Pregnancy Prevention Program Checklist to document your inability to become pregnant.

Women who are not able to become pregnant include:

- Women who are at least 50 years old and have been naturally postmenopausal for at least 1 year

- Women who have premature ovarian failure confirmed by a specialist gynaecologist

- Women with previous bilateral salpingo-oophorectomy, or hysterectomy

- Women with XY genotype, Turner syndrome, or uterine agenesis

Special warnings for male patients

Before starting treatment, your doctor will complete the Pregnancy Prevention Program Checklist to document that you have been advised that your partner must AVOID becoming pregnant while you are being treated with lenalidomide and for at least 7 days after treatment has ended.

Lenalidomide passes into human semen. If your partner is pregnant or of childbearing potential and not using effective contraceptive methods, you will need to use condoms **throughout treatment, during treatment breaks, and for at least 7 days after treatment is finished, even if you have undergone a vasectomy.**

If your partner becomes pregnant while you are taking lenalidomide or within 7 days of stopping treatment, you must notify your prescriber immediately. It is recommended that your partner be referred to a specialist doctor or doctor with experience in teratology for advice and evaluation.

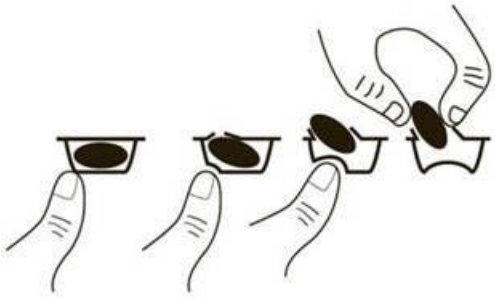
You should **NOT** donate semen or sperm during treatment and for at least 7 days after stopping treatment with lenalidomide.

HOW TO HANDLE THE MEDICINAL PRODUCT: ADVICE TO PATIENTS AND THOSE WHO ASSIST THEM (Caregivers)

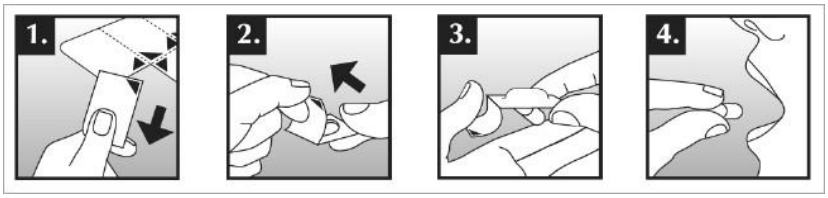
Keep the medicine in the original package and make sure it is not damaged and/or broken when taking it out.

Lenalidomide can come in different types of packs/blisters.

If lenalidomide comes in hard capsules inside a non-peelable blister, to extract the capsule, it is recommended to press on one side only, at one end of the capsule (see figure below) as the pressure applied in the middle or on both ends at the same time could cause deformation and breakage of the capsule itself.



If lenalidomide comes as hard capsules in a peelable blister, to remove the capsule, hold the blister by the edges and separate one end of the blister from the rest of the blister by gently tearing along the perforations around it (1). Lift the edge of the film and peel off the film completely (2). Turn the capsule onto your hand (3). Swallow the capsule whole, preferably with water (4).



Patients and/or caregivers should wear disposable gloves when handling the product. Gloves should then be carefully removed to prevent skin exposure, placed in a sealable polyethylene bag, and disposed of in accordance with local requirements. Hands should then be washed thoroughly with soap and water. Women who are known or suspected to be pregnant should not handle the blister or capsule.

Further details are available below.

Warnings for patients and/or caregivers

Use the following precautions to prevent potential drug exposures during handling:

- If you are pregnant or think you may be pregnant, you must not handle the blister or capsule.
- Wear disposable gloves when handling the medicine and/or the packaging (e.g. blisters and/or capsules).
- Use proper glove removal technique to prevent potential skin exposure (see corresponding illustration below).
- Place the gloves in a sealable polyethylene bag and dispose of according to local regulations.
- After removing gloves, wash hands thoroughly with soap and water.

If the drug package appears visibly damaged, use the following additional precautions to prevent exposure:

- If the outer packaging is visibly damaged – **Do not open it.**
- If the blister foils are damaged or cracked or the capsules appear to be damaged or cracked – **Close the outer carton immediately.**
- Place the product inside a sealable polyethylene bag.
- Return the unused pack to your pharmacist as soon as possible to ensure safe disposal.

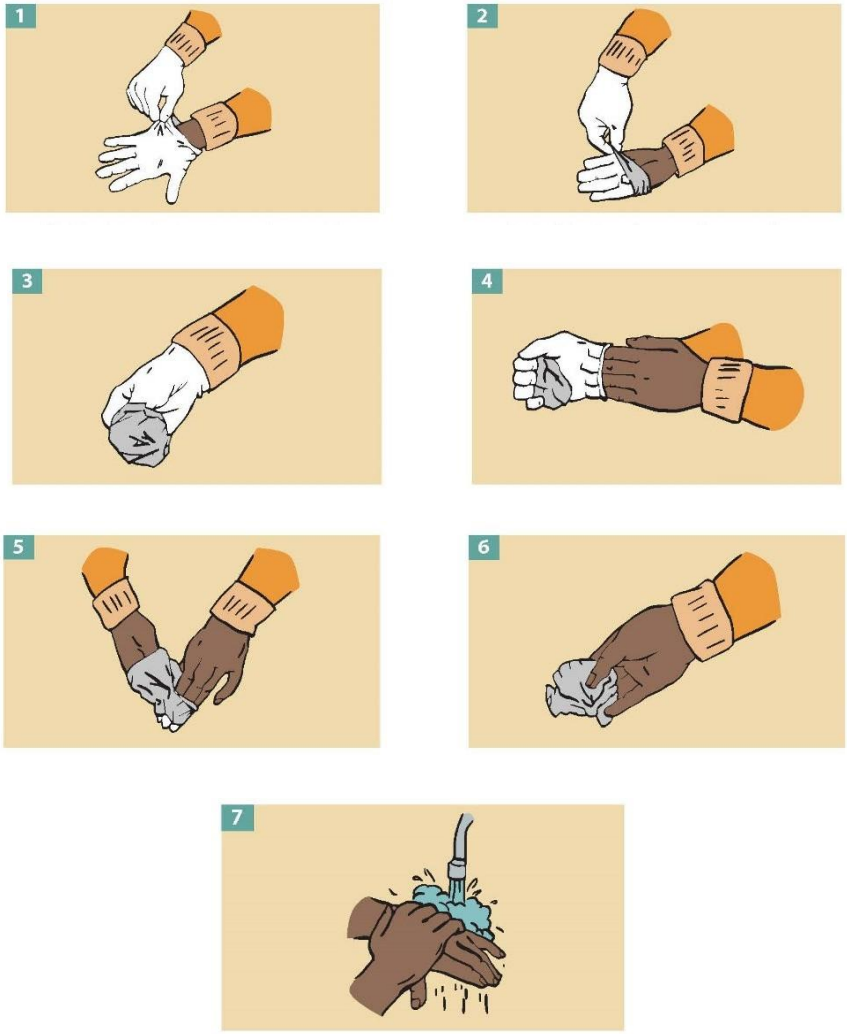
If the product has spilled or leaked, use adequate precautions to minimize possible exposure by adopting personal protection measures:

- If the capsules are crushed or broken, the powder containing lenalidomide may have leaked out. Avoid dispersing dust and avoid breathing dust.
- Wear disposable gloves to collect the dust.
- Place a damp cloth or tarp over the area where the dust is present to minimize dust kicking into the air. Further wet the cloth to allow the material to enter the solution. Then clean the affected area thoroughly with soap and water and dry it.
- Place all contaminated materials including drape or wet cloth and gloves in a sealable polyethylene bag and dispose of in accordance with local regulations.
- Wash hands thoroughly with soap and water after removing gloves.
- Report the incident immediately to the prescriber and/or pharmacist.

If the contents of the capsules come into contact with the skin or mucous membranes:

- If you have come in contact with the powder containing lenalidomide, wash the exposed area thoroughly with soap and running water.
- If the dust gets into your eyes, immediately flush your eyes with large amounts of water for at least 15 minutes. If you wear contact lenses, remove the lenses and discard them before flushing your eyes with water. In case of irritation, contact an ophthalmologist.

Proper glove removal technique



- Grasp the outer edge near the wrist (1).
- Remove from the hand by turning the glove inside out (2).
- Hold the removed glove in your hand still wearing the glove (3).
- Slip the fingers of the ungloved hand under the wrist of the other glove, being careful not to touch the outside of the glove (4).
- Remove from the inside, creating a bag that contains both gloves (5).
- Dispose of it in a suitable container (6).
- Wash your hands thoroughly with soap and water (7).

This document has been approved by HSA on 19 Feb 2024
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