• PREGNANCY PREVENTION PROGRAM •

PATIENT MEDICATION GUIDE
FOR IMMUNOMODULATORY AGENTS

Revlimid® (Lenalidomide) and Pomalyst® (Pomalidomide)

Patient Medication Guide for Lenalidomide and Pomalidomide

You have been prescribed Revlimid® (lenalidomide) or Pomalyst® (pomalidomide), which are also called immunomodulatory agents. This type of treatment can cause birth defects. It is extremely important that you do not take them if you are pregnant, or planning to become pregnant. If you are able to become pregnant and are not using an effective contraceptive (birth control) method, do not use this treatment. This medication guide is to help ensure safe use and handling of the immunomodulatory agent.

If used during pregnancy, the immunomodulatory agents, lenalidomide and pomalidomide, can harm the developing fetus. Potential risks include loss of the fetus and birth defects. Please make sure that you have read and understood the following information prior to starting treatment with lenalidomide or pomalidomide. If you have any questions or concerns about your treatment, please reach out to your healthcare professional.

Bristol Myers Squibb™

Pomalyst® (pomalidomide) capsules

Revlimid® (lenalidomide) capsules

For all patients:

- You should never share your medicine with anyone else.
- You should store your medicine safely so that no one else can take the medicine by accident. Ensure that the medicine is out of reach of children.
- You should not open, crush, or overly handle the capsules.
- You should always return of any unused capsules to pharmacist for safe disposal at the end of your treatment.
- For more information on safe handling of the medicine, please refer to the section below on Handling Precautions.
- You should not donate blood during treatment, even during dose interruptions, and for at least 7 days after stopping treatment.
- If you experience any side effects while taking lenalidomide or pomalidomide, you should tell your healthcare professional.
- You must never take lenalidomide or pomalidomide if:
    1. You are pregnant, or
    2. You are able to become pregnant, even if you are not planning to, unless all of the conditions of the Pregnancy Prevention Programas outlined in this medication guide are met.

Handling Precautions

- The capsules should not be opened, crushed or overly handled.
- If powder from lenalidomide or pomalidomide makes contact with the skin, the skin should be washed immediately and thoroughly with soap and water.
- If powder from lenalidomide or pomalidomide makes contact with the mucous membranes, (moist inner lining of some body parts such as the nose and mouth), they should be thoroughly flushed with water.
- Caregivers 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.

PREGNANCY PREVENTION PROGRAM

If you are a woman who is able to become pregnant:

- You must use at least one effective method of contraception for at least 4 weeks before starting treatment, throughout the duration of your treatment, even during dose interruptions, and for at least 4 weeks after stopping treatment. Your healthcare professional will advise you on appropriate methods of contraception. Some types of

contraception are not recommended during treatment with lenalidomide and pomalidomide. That's why it's essential that you discuss this with your healthcare professional. The following methods are examples of effective contraception:

- implant,
- levonorgestrel-releasing intrauterine system,
- medroxyprogesterone acetate depot,
- tubal sterilization,
- sexual intercourse with a vasectomized male partner only (vasectomy must be confirmed by two negative semen analyses),
- ovulation inhibitory progesterone-only pills (i.e. desogestrel)

OR

- You agree and confirm every month that you will NOT engage in heterosexual intercourse.

AND

- You will have pregnancy tests under the supervision of your healthcare professional before treatment. These will be repeated at least every 4 weeks during treatment, even during dose interruptions, and at least 4 weeks after the treatment has finished (unless it is confirmed that you have had a tubal sterilization), even if you confirm absolute and continuous sexual abstinence from heterosexual intercourse on a monthly basis.
- You should start treatment as soon as possible after a negative pregnancy test result and having received your medication.
- Inform your healthcare professional of a missed menstrual period, any unusual menstrual bleeding, or if you believe you may be pregnant. If you become pregnant while on lenalidomide or pomalidomide, you must stop treatment immediately and inform your healthcare professional immediately. They may recommend that you see a type of healthcare professional specializing in developmental abnormalities of the fetus.
- You should inform the healthcare professional prescribing your contraception about your treatment with lenalidomide or pomalidomide. If a change in the contraception method is needed, you should inform the healthcare professional prescribing your lenalidomide or pomalidomide treatment.

If you are a male:

- You must use condoms even if you have had a vasectomy as seminal fluid may still contain the medicine in the absence of spermatozoa, throughout the duration of your treatment, even during dose interruptions, and for at least 7 days after stopping treatment if your partner is pregnant or can become pregnant and not using effective contraception.
- You must not donate semen or sperm during treatment, even during dose interruptions, and for at least 7 days after stopping treatment as the medicine can pass into seminal fluid.
- You should inform your treating healthcare professional immediately if your partner becomes pregnant while you are taking or within 7 days after you have stopped taking lenalidomide or pomalidomide. Your partner should also inform her healthcare

professional immediately. It is recommended that she be referred to a healthcare professional specializing in abnormalities of the fetus for evaluation and advice.

Please see the back of this medication guide for your healthcare professional's contact information.

Risks of low platelet numbers (thrombocytopenia) and bleeding

- Lenalidomide and pomalidomide can cause the number of platelets (cells which are responsible for making the blood clot properly) to be reduced (thrombocytopenia).
- Your doctor may monitor your blood cell numbers during treatment and do some blood tests regularly and will check your general condition to make sure the medicine is working and may adjust your dose accordingly.
- Inform your healthcare professional immediately if you experience any bleeding (including nosebleeds) or bruising more easily than normal.

Like all medicines, side effects may be experienced, although not everybody gets them. Some side effects are more common than others and some are more serious than others. Ask your healthcare professional if you would like more information, such as the side effects, for the product you are prescribed (Revlimid® (lenalidomide) or Pomalyst® (pomalidomide)).

Talk to your healthcare professional if you experience any side effects during your treatment with either Revlimid® (lenalidomide) or Pomalyst® (pomalidomide) or if they get worse.

Important Contact Information

I have been prescribed Revlimid® / Pomalyst® (circle one)

My healthcare professional who prescribed Revlimid®/ Pomalyst®(circle one):

• Please complete this form in BLOCK CAPITAL LETTERS.

First Name	:
Last Name	:
Institution Address	:
Email Address	:

Additional healthcare professional: :

• Please complete this form in BLOCK CAPITAL LETTERS.

First Name	:
Last Name	:
Institution Address	:
Email Address	:

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