

# PATIENT GUIDE TO LEAVDO RISK MANAGEMENT PROGRAM (RMP)

Your doctor has prescribed you with LEAVDO (lenalidomide) for the treatment of multiple myeloma (blood cancer). This Patient Guide provides you with important information about the risks associated with LEAVDO and the requirements of the LEAVDO Risk Management Program (RMP) to ensure safe use of LEAVDO. Please make sure that you have read and understood the information in this guide prior to starting treatment with LEAVDO. You must adhere to the program requirements to receive LEAVDO treatment. If you have questions or concerns about your treatment, please consult your doctor.

## RISKS ASSOCIATED WITH LEAVDO

### 1. Teratogenicity

LEAVDO can cause severe and life-threatening birth defects (deformed babies) or death of an unborn baby.

If you are pregnant or planning to become pregnant, you **MUST NOT TAKE LEAVDO**.

### 2. Thrombocytopenia (low platelet numbers) and bleeding

- LEAVDO can cause a reduction in the number of platelets (cells which are responsible for making the blood clot properly).
- Your doctor may order blood tests regularly to monitor your blood cell numbers during treatment, and may adjust your dose accordingly.
- Seek medical help if you experience any unexpected bleeding (including nosebleeds) or bruising.

## ABOUT THE LEAVDO RMP

- To prevent serious risks to unborn babies, LEAVDO is only available through a restricted distribution program known as the LEAVDO Risk Management Program (RMP). To be eligible for LEAVDO treatment, you must agree to adhere to the requirements of the LEAVDO RMP.
- Your doctor will explain **BOTH** this Patient Guide and the Patient Letter of Consent for LEAVDO RMP (LOC) to you.
- You should **complete and sign** the Patient LOC after reading this Patient Guide and agreeing to the requirements of the LEAVDO RMP as stated in the Patient LOC.

## GENERAL GUIDELINES

1. Do not donate blood during treatment (including during dose interruptions) and for at least 7 days after last dose.
2. Any unused medication at the end of treatment must be returned to pharmacy/ clinic for safe disposal.
3. Do not share your medicine with anyone else, even if they have similar symptoms.
4. Store your medicine below 30°C away from others and out of reach of children.
5. Inform your doctor if you experience any side effects during LEAVDO therapy.

## HANDLING PRECAUTIONS

- The capsules should not be opened, crushed or overly handled.
- If powder content makes contact with the skin, the skin should be washed immediately and thoroughly with soap and water.
- If powder content 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. 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.**

**Warning:** LEAVDO may lead to additional health issues known as side effects. Ask your doctor about other potential side effects linked to LEAVDO. Be sure to report all side effects to your doctor immediately.

**Disclaimer:** This summary does not cover all the risks associated with using LEAVDO. Please consult your doctor for more detailed information on the potential risks.

## **FEMALE PATIENTS OF CHILDBEARING POTENTIAL (even if they have amenorrhea or irregular menstrual periods)**

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

- Use **at least one effective contraception (birth control)** for at least 4 weeks before, during, and until at least 4 weeks after the last dose of treatment (including dose interruption). Discuss with your doctor on the type of contraception as some types of contraception are not recommended during LEAVDO therapy.

### **Examples of effective methods of 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**

Commit to absolute and continuous abstinence from heterosexual intercourse

- Perform pregnancy tests under the supervision of your healthcare professional before starting your treatment. These will be repeated at least every 4 weeks during treatment (including dose interruptions), and at least 4 weeks after the last dose (unless it is confirmed that you have had a tubal sterilization), even if you confirm absolute and continuous sexual abstinence from heterosexual intercourse.
- Commence LEAVDO therapy immediately upon confirmation of negative pregnancy test results.
- Inform all healthcare professionals involved in your care that you are on LEAVDO therapy
- Discuss first with your doctor if you need to change or stop your contraception
- Stop taking LEAVDO and **INFORM YOUR DOCTOR IMMEDIATELY** if you become pregnant while taking LEAVDO; or if you miss your menstrual period or experience unusual menstrual bleeding; or think for any reason that you may be pregnant

## **MALE PATIENTS**

If you are a male, you must:

- Use condoms (even if you have undergone vasectomy as LEAVDO has been detected in seminal fluid) throughout treatment duration, during dose interruptions, and for at least 7 days after stopping your treatment if your partner is pregnant or can become pregnant and is not using effective contraception.  
*Effective contraceptive methods your female partner can use include 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 pill (i.e. desogestrel).*
- Not donate semen or sperm during treatment, including during dose interruptions and for at least 7 days after stopping your treatment as LEAVDO can pass into seminal fluid.
- Inform your doctor immediately if your partner becomes pregnant while you are on treatment with LEAVDO or within 7 days after you have stopped taking LEAVDO. Your partner should also inform her doctor immediately. It is recommended that she be referred to a gynecologist for evaluation and advice.

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