



LENLI

Patient Brochure



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You have been given this booklet because your doctor has prescribed Lenli (lenalidomide) for you and **Lenli is expected to be harmful to the unborn child.**

Please refer to the following sections of this brochure for important information about how to avoid the risk of foetal exposure for patients receiving Lenli:

- For women who are able to become pregnant, please refer to sections 1 & 4.
- For women who are NOT able to become pregnant, please refer to sections 2 & 4.
- For men, please refer to sections 3 & 4.

Section 1

For Women who are able to become pregnant*

Important: Do NOT become pregnant:

- During the 4 weeks before starting Lenli treatment
- While taking Lenli
- During any interruption in Lenli treatment
- During the 4-week period following the conclusion of your Lenli treatment
- Do not take Lenli if you are pregnant or think you may be pregnant or planning to become pregnant, as Lenli is expected to be harmful to an unborn child

Before starting treatment:

- In order to ensure that an unborn baby is not exposed to Lenli, your doctor will complete a Patient Agreement Form documenting that you have been informed of the requirement for you NOT to become pregnant during treatment with Lenli and for one month after finishing Lenli.
- You must use two effective methods of birth control (contraception)† during the 4-week period before starting Lenli.
- You must have one negative medically supervised pregnancy test confirmed by your doctor.
 - Either at the time of consultation, or in the 3 days prior to the visit to the doctor.
 - The pregnancy test must be medically supervised and not a pregnancy test from a pharmacy.

*Includes: women who are menstruating, amenorrhoeic due to previous medical treatment, <50 years of age and/or peri-menopausal; women who have not been in natural menopause for 12 consecutive months.

†Suitable methods of contraception include Implant; Levonorgestrel-releasing intrauterine system (IUS); Medroxyprogesterone acetate depot; Tubal sterilisation; Sexual intercourse with a vasectomised male partner only; vasectomy must be confirmed by two negative semen analyses; Ovulation inhibitory progesterone-only pills (i.e. desogestrel).

‡Combined oral contraceptives are not recommended. Please ask your doctor which birth control method you should use.

During treatment (including treatment interruption):

- You must ensure that you receive your Lenli within 7 days after being prescribed otherwise you will need a new prescription.
- You should start Lenli treatment as soon as possible after having a negative pregnancy test result.
- To prevent a pregnancy you must either:
 - continue to use two effective methods of birth control (contraception), or
 - agree you will NOT engage in sexual activity with a male Partner.
- You must also undergo regular medically supervised pregnancy tests, regardless of whether continuous abstinence is practised
 - At least every 4 weeks during treatment,
And
 - The pregnancy tests should be performed on the day of the visit to the doctor or in the 3 days prior to the visit.
- You must not breastfeed or donate blood.
- Never share your Lenli capsules.

Note: If you miss a period, experience any abnormality in menstrual bleeding, become pregnant, suspect pregnancy or have sexual intercourse without using an effective means of birth control (contraception):

- **Stop taking your Lenli immediately, tell your doctor straight away and have a pregnancy test.**

For 4 weeks after treatment:

- You must continue to use two effective methods of birth control (contraception).
- You must continue the medically supervised pregnancy tests at least every 4 weeks, ensuring that a pregnancy test is conducted at least 4 weeks after stopping treatment.
- You must not breastfeed or donate blood.

Note: If you miss a period, experience any abnormality in menstrual bleeding, become pregnant, suspect pregnancy or have sexual intercourse without using an effective means of birth control (contraception):

- **Tell your doctor immediately and have a pregnancy test.**

Section 2

For Women Patients who are NOT able to become pregnant IMPORTANT TO REMEMBER:

- **Lenli may cause birth defects or death to unborn babies.**
- **Pregnant women must NOT take Lenli.**

Before starting treatment:

In order to ensure that an unborn baby is not exposed to Lenli, your doctor will complete a Patient Agreement Form documenting that you are not able to become pregnant.

This means that you are:

- at least 50 years old and have been naturally postmenopausal for at least 12 months OR
- have premature ovarian failure confirmed by a specialist gynaecologist OR
- have had your uterus removed (hysterectomy) OR
- have had both fallopian tubes and ovaries removed OR
- have XY genotype OR have Turner Syndrome OR
- have uterine agenesis

During treatment:

- You must not donate blood.
- Never share your Lenli capsules.

For at least 4 weeks after treatment:

- You must not donate blood.

Section 3**For Male Patients****IMPORTANT TO REMEMBER:**

- **Lenli may cause birth defects or death to unborn babies.**
- **Men must NOT cause pregnancy.**

Before starting treatment:

- In order to ensure that an unborn baby is not exposed to Lenli, your doctor will complete a Patient Agreement Form documenting that you have been informed of the requirements for your partner NOT to become pregnant during treatment with Lenli and for at least 4 weeks after you finish Lenli.

During treatment:

- Lenli passes into human semen. If your partner is pregnant or able to become

pregnant, and she does not use effective contraception, you must use a condom EVERY TIME you have sexual intercourse with a woman who either is or can become pregnant (even if you have had a successful vasectomy).

- You must tell your doctor immediately if you have sexual intercourse with a woman without using a condom, or if you think for any reason that your partner may be pregnant.
- You must not donate blood or sperm.
- Never share your Lenli capsules.

For 4 weeks after treatment:

- You must continue to use a condom EVERY TIME you have sexual intercourse with a woman who either is or can become pregnant (even if you have had a successful vasectomy). You must tell your doctor if you have sexual intercourse with a woman without using a condom, or if you think for any reason that your partner may be pregnant.
- You must not donate blood or sperm.

Note: You must contact your Doctor or hospital team urgently if you suspect that your Partner is pregnant.

Section 4

Information for All Patients:

How and When to take Lenli

- Lenli must be given to you by healthcare professionals with experience in treating multiple myeloma.
- You should swallow the Lenli capsules whole, preferably with water.
- Do not break, open or chew the capsules. The Lenli capsules can be taken either with or without food.
- You should take Lenli at about the same time on the scheduled days.
- Always take Lenli exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

What to do if you forget to take your Lenli:

If you forget to take Lenli at your regular time and

- Less than 12 hours have passed: take your capsule immediately.
- More than 12 hours have passed: do not take your capsule. Take your next capsule at the usual time the next day.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

How To Store Lenli Safely

- Keep this medicine out of the sight and reach of children.
- Do not use Lenli after the expiry date, which is stated on the blister after “EXP”.
- The expiry date refers to the last day of that month.
- Do not use this medicine if you notice any damage or signs of tampering to the pack.
- Do not throw away any medicines via wastewater or household waste.
- All unused Lenli capsules should be returned to the pharmacist. These measures will help protect the environment.

Other information

- You should never share Lenli with anyone else.
- You should not donate blood during treatment and for at least 4 weeks after treatment finishes.
- The most common, serious side effects of Lenli 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 before treatment, weekly for at least the first 8 weeks of treatment and at least every month after that. Lenli may also cause 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, e. g., 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 Lenli you should tell your doctor or pharmacist.

For More Information

- Contact your doctor or hospital team immediately if you experience any side effects.
- Speak with your doctor or pharmacist for more information about Lenli.
- Contact your doctor or hospital team urgently if you suspect that you or your partner is pregnant.



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