



# LENLI

## Healthcare Professional Information Pack



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### Indications

#### Multiple myeloma

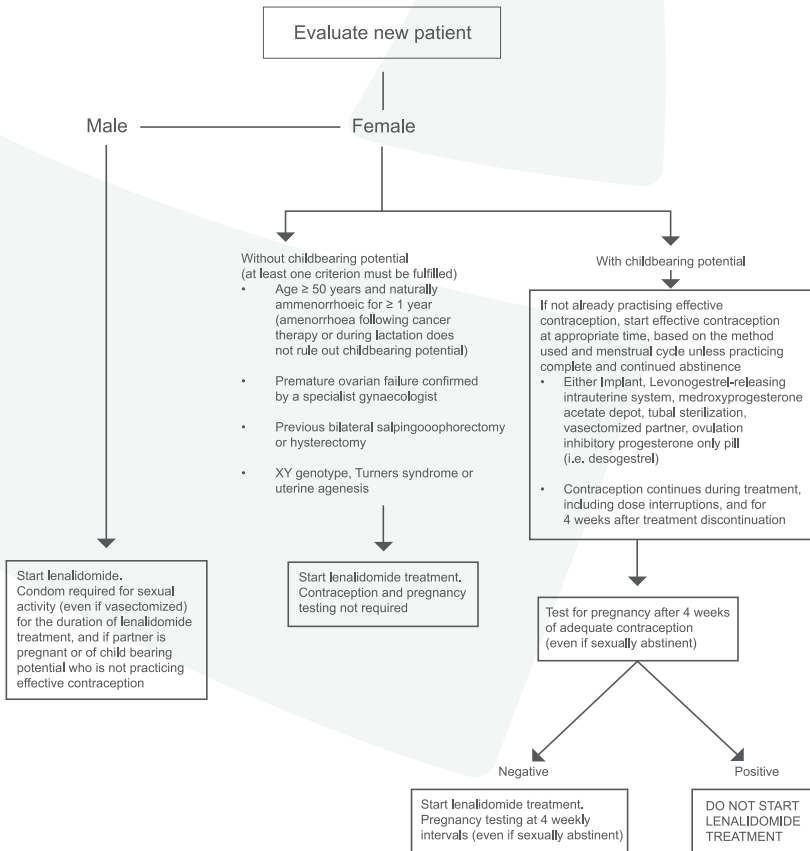
- Lenli as monotherapy is indicated for the maintenance treatment of adult patients with newly diagnosed multiple myeloma who have undergone autologous stem cell transplantation.
- Lenli as combination therapy with dexamethasone is indicated for the treatment of adult patients with previously untreated multiple myeloma who are not eligible for transplant.
- Lenli in combination with dexamethasone is indicated for the treatment of multiple myeloma in adult patients who have received at least one prior therapy.

### Introduction

- Lenalidomide is structurally related to thalidomide. Thalidomide is a known human teratogenic substance that causes severe life-threatening birth defects. Lenalidomide induced in monkeys' malformations similar to those described with thalidomide. An embryofoetal development study has been conducted in monkeys administered lenalidomide at doses up to 4 mg/kg/day. Findings from this study showed that lenalidomide produced external malformations including non-patent anus and malformations of upper and lower extremities (bent, shortened, malformed, malrotated and/or absent part of the extremities, oligo and/or polydactyly) in the offspring of female monkeys who received the drug during pregnancy. If lenalidomide is taken during pregnancy, a teratogenic effect can be expected. Therefore, lenalidomide is contraindicated in pregnancy and in women of childbearing potential unless the conditions of the Pregnancy Prevention Programme described in this brochure are carried out.
- All men and all women of childbearing potential should undergo counselling of the need to avoid pregnancy (checklists for counselling are provided with this pack).
- Patients should be capable of complying with the requirements of safe use of lenalidomide.
- Patients must be provided with appropriate Lenli patient brochure and Lenli Patient Agreement Form.

## Pregnancy Prevention Programme

- The Pregnancy Prevention Programme is set out in the following Algorithm:



- The following are considered not to have childbearing potential.  
A female patient or a female partner of a male patient is considered not to have childbearing potential if she meets at least one of the following criteria:
  - Age  $\geq 50$  years and naturally amenorrhoeic for  $\geq 1$  year (Amenorrhoea following cancer therapy or during breast-feeding does not rule out childbearing potential).
  - Premature ovarian failure confirmed by a specialist gynaecologist.
  - Previous bilateral salpingo-oophorectomy, or hysterectomy.
  - XY genotype, Turner syndrome, uterine agenesis.
- You are advised to refer your patient for a gynaecological opinion if you are unsure whether or not she meets these criteria.

## Safety Advice for Women of Childbearing Potential

### Counselling

For women of childbearing potential, lenalidomide is contraindicated unless all of the following are met:

- She understands the expected teratogenic risk to the unborn child.
- She understands the need for effective contraception, without interruption, at least 4 weeks before starting treatment, throughout the entire duration of treatment, and at least 4 weeks after the end of treatment.
- Even if a woman of childbearing potential has amenorrhea she must follow all the advice on effective contraception.
- She should be capable of complying with effective contraceptive measures.
- She is informed and understands the potential consequences of pregnancy and the need to rapidly consult if there is a risk of pregnancy.
- She understands the need to commence the treatment as soon as lenalidomide is dispensed following a negative pregnancy test.
- She understands the need and accepts to undergo pregnancy testing at least every 4 weeks except in case of confirmed tubal sterilisation.
- She acknowledges that she understands the hazards and necessary precautions associated with the use of lenalidomide.

### Pregnancy testing

According to local practice, medically supervised pregnancy tests with a minimum sensitivity of 25 mIU/mL must be performed for women of childbearing potential as outlined below. This requirement includes women of childbearing potential who practice absolute and continuous abstinence. Ideally, pregnancy testing, issuing a prescription and dispensing should occur on the same day. Dispensing of lenalidomide to women of childbearing potential should occur within 7 days of the prescription.

- Prior to starting treatment.  
A medically supervised pregnancy test should be performed during the consultation, when lenalidomide is prescribed, or in the 3 days prior to the visit to the prescriber once the patient had been using effective contraception for at least 4 weeks. The test should ensure the patient is not pregnant when she starts treatment with lenalidomide.
- Follow-up and end of treatment.  
A medically supervised pregnancy test should be repeated at least every 4 weeks, including at least 4 weeks after the end of treatment, except in the case of confirmed tubal sterilisation. These pregnancy tests should be performed on the day of the prescribing visit or in the 3 days prior to the visit to the prescriber.

### Contraception

Women of childbearing potential must use two effective method of contraception

for at least 4 weeks before therapy, during therapy, and until at least 4 weeks after lenalidomide therapy and even in case of dose interruption unless the patient commits to absolute and continuous abstinence confirmed on a monthly basis. If not established on effective contraception, the patient must be referred to an appropriately trained health care professional for contraceptive advice in order that contraception can be initiated.

The following can be considered to be examples of suitable methods of contraception:

- 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)

Because of the increased risk of venous thromboembolism in patients with multiple myeloma taking lenalidomide and dexamethasone, and to a lesser extent in patients with multiple myeloma taking lenalidomide monotherapy, combined oral contraceptive pills are not recommended. If a patient is currently using combined oral contraception the patient should switch to one of the effective methods listed above. The risk of venous thromboembolism continues for 4–6 weeks after discontinuing combined oral contraception. The efficacy of contraceptive steroids may be reduced during co-treatment with dexamethasone).

Implants and levonorgestrel-releasing intrauterine systems are associated with an increased risk of infection at the time of insertion and irregular vaginal bleeding. Prophylactic antibiotics should be considered particularly in patients with neutropenia.

Copper-releasing intrauterine devices are generally not recommended due to the potential risks of infection at the time of insertion and menstrual blood loss which may compromise patients with neutropenia or thrombocytopenia.

## Safety Advice for Men

For male patients taking lenalidomide, pharmacokinetic data has demonstrated that lenalidomide is present in human semen at extremely low levels during treatment and is undetectable in human semen 3 days after stopping the substance in the healthy subject. As a precaution and taking into account special populations with prolonged elimination time such as renal impairment, all male patients taking lenalidomide must meet the following conditions:

- Understand the expected teratogenic risk if engaged in sexual activity with a pregnant woman or a woman of childbearing potential.
- Understand the need for the use of a condom if engaged in sexual activity with a pregnant woman or a woman of childbearing potential not using effective

contraception (even if the man has had a vasectomy), during treatment and for at least 4 weeks after dose interruptions and/or cessation of treatment.

- Understand that if his female partner becomes pregnant whilst he is taking Lenalidomide or shortly after he has stopped taking Lenalidomide, he should inform his treating physician immediately and that it is recommended to refer the female partner to a physician specialised or experienced in teratology for evaluation and advice.

## Requirements in the event of a suspected pregnancy

- ✓ Stop treatment if female patient.
- ✓ Refer patient to a physician specialised or experienced in teratology for evaluation and advice.
- ✓ Notify Alvogen of all such occurrences using the Lenli Pregnancy Reporting Form included in this pack.
- ✓ Alvogen will wish to follow-up with you the progress of all pregnancies.
- ✓ Report the event to the National Health Authority as per applicable local guidelines.

## Reporting of Adverse Reactions

The safe use of lenalidomide is of paramount importance. As part of Alvogen's ongoing safety monitoring, the company wishes to learn of adverse reactions that have occurred during the use of lenalidomide. Adverse events should be reported to Alvogen via the following contact details.

### Local Country Contact Details

Lotus International Pte. Ltd.

Email: [drugsafety.sg@lotuspharm.com](mailto:drugsafety.sg@lotuspharm.com)

Adverse events should also be reported to Health Sciences Authority via their online reporting portal (<https://www.hsa.gov.sg/adverse-events>). Please also send a copy of the submitted HSA adverse event reporting form to Alvogen.

## Enclosures

- ✓ Lenli Communication Plan
- ✓ Lenli Patient Agreement Form
- ✓ Lenli Prescription Form
- ✓ Lenli Pregnancy Reporting Form
- ✓ Lenli Patient Brochure
- ✓ Lenli Product Insert

This document has been approved by HSA as of 8 Dec 2021.

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