



LENALIDOMIDE SPC® (Lenalidomide)

# PATIENT BROCHURE

*This document has been approved by the Saudi Food and Drug Authority (SFDA).*

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# Introducing

Your Doctor intends to prescribe LENALIDOMIDE SPC® for you.

LENALIDOMIDE SPC® (the trade name for lenalidomide) is a structural analogue to Thalidomide. Thalidomide is a known teratogen that causes severe life-threatening human birth defects. If LENALIDOMIDE SPC® is taken during pregnancy it may cause birth defects or death to an unborn baby.

To avoid fetal exposure, LENALIDOMIDE SPC® is available only under a special distribution program

The program is designed to ensure that LENALIDOMIDE SPC® therapy is always prescribed and taken in the recommended way.

Key features of the program:

- Only physicians registered with program can prescribe LENALIDOMIDE SPC®.
- Only pharmacists/pharmacies registered with program can dispense LENALIDOMIDE SPC®.
- Only patient who have been formally enrolled in the program can receive LENALIDOMIDE SPC®.

To enroll, patients must sign a "LENALIDOMIDE SPC® Treatment Initiation Form"

## Special Requirements for Females who are Able to Become Pregnant



### Include:

- Females younger than 50 years
- Females that are not naturally postmenopausal for at least two years
- Females that have not had a hysterectomy

### Important: do NOT become pregnant:

- During the four weeks before starting LENALIDOMIDE SPC® treatment
- While taking LENALIDOMIDE SPC®
- During any interruption in LENALIDOMIDE SPC® treatment
- During the four-week period following the conclusion of your LENALIDOMIDE SPC® treatment

### Before starting treatment:

1. You must sign a "LENALIDOMIDE SPC® Treatment Initiation Form", agreeing not to become pregnant while taking LENALIDOMIDE SPC®
2. You must use two reliable methods of birth control (contraception) at the same time 4 weeks before starting LENALIDOMIDE SPC® treatment. Refer below for examples of suitable methods of contraception:
  - Highly effective methods
    - » Intra Uterine Device (IUD)
    - » Hormonal (hormonal implants, levonorgestrel-releasing intrauterine system (IUS), medroxyprogesterone acetate depot injections, ovulation inhibitory progesterone-only pills e.g. desogestrel )
    - » Tubal ligation
    - » Partner's vasectomy
  - Effective methods
    - » Male condom
    - » Diaphragm
    - » Cervical cap



### IMPORTANT TO REMEMBER

LENALIDOMIDE SPC® may cause birth defects or death to unborn babies.

#### Contraceptive methods must include:

- At least 1 highly effective method and 1 additional effective barrier method used at the same time.
- You must have a medically supervised pregnancy test done during your consultation with the doctor, when LENALIDOMIDE SPC® is prescribed, or in the 3 days prior to the visit to the doctor once you had been using effective contraception for at least 4 weeks. The test should ensure that you are not pregnant when you start treatment with LENALIDOMIDE SPC®
- You must agree to not breastfeed or donate blood
- You must agree to never share your LENALIDOMIDE SPC® capsules
- You must agree to return unused LENALIDOMIDE SPC® capsules to your pharmacist.

#### During treatment and dose interruptions:

- You must continue to use two reliable methods of birth control (contraception) at the same time during treatment and during any interruption in LENALIDOMIDE SPC® treatment
- You must also undergo regular medically supervised pregnancy tests every four weeks during treatment
- You must not breastfeed or donate blood
- Never share your LENALIDOMIDE SPC® capsules



#### NOTE

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

- Stop LENALIDOMIDE SPC® immediately
- Tell your doctor
- Have a pregnancy test

#### For four weeks after treatment:

- You must continue to use two reliable methods of birth control (contraception) at the same time
- You must not breastfeed or donate blood
- Never share your LENALIDOMIDE SPC® capsules
- Return unused LENALIDOMIDE SPC® capsules to your pharmacist
- You must undergo a medically supervised pregnancy test 4 week after discontinuation of LENALIDOMIDE SPC® therapy



#### NOTE

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

- Tell your doctor
- Have a pregnancy test

## Requirements for Females who are NOT Able to Become Pregnant



#### Include:

Females who do not meet the below definition of Female NOT of childbearing potential should be classified as Females of Childbearing Potential (FCBP).

- Females  $\geq$  50 years old and naturally amenorrheic for  $\geq$  2 years
  - » Amenorrhea following cancer therapy does not rule out childbearing potential
- Females that have premature ovarian failure confirmed by a gynecologist
- Females with bilateral salpingo-oophorectomy or hysterectomy
- Females with XY genotype, Turner's syndrome or uterine agenesis

#### Before starting treatment:

- You must sign a "LENALIDOMIDE SPC® Treatment Initiation Form", indicating that you are not pregnant and do not have the ability to have children.
- You must agree to not donate blood
- You must agree to never share your LENALIDOMIDE SPC® capsules
- You must agree to return unused LENALIDOMIDE SPC® capsules to your pharmacist

#### During treatment and during dose interruptions:

- You must not donate blood
- Never share your LENALIDOMIDE SPC® capsules



#### For four weeks after treatment:

- You must not donate blood
- Return unused LENALIDOMIDE SPC® capsules to your pharmacist

## Requirements for Male Patients

#### Before starting treatment:

LENALIDOMIDE SPC® is present in semen. You must sign a "LENALIDOMIDE SPC® Treatment Initiation Form", agreeing 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) and will follow all requirements, including the following:

- You must agree to not donate blood, sperm or semen
- You must agree to never share your LENALIDOMIDE SPC® capsules
- You must agree to return unused LENALIDOMIDE SPC® capsules to your pharmacist

#### During treatment and during dose interruptions:

- 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 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, sperm or semen
- Never share your LENALIDOMIDE SPC® capsules

#### For four 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, sperm or semen
- Never share your LENALIDOMIDE SPC® capsules
- Return unused LENALIDOMIDE SPC® capsules to your pharmacist



## SPECIAL WARNINGS AND PRECAUTIONS

Low white blood cells (neutropenia) and low platelets (thrombocytopenia).

LENALIDOMIDE SPC® causes low white blood cells and low platelets in most patients. You may need a blood transfusion or certain medicines if your blood counts drop too low. If you are being treated for del 5q myelodysplastic syndromes (MDS) your blood counts should be checked weekly during the first 8 weeks of treatment with LENALIDOMIDE SPC®, and at least monthly thereafter. If you are being treated for multiple myeloma, your blood counts should be checked every 2 weeks for the first 12 weeks and then at least monthly thereafter.

**A higher chance for blood clots in your veins and lungs.**

Call your healthcare provider or get medical help right away if you get any of these signs or symptoms:

- shortness of breath
- chest pain
- arm or leg swelling

## POSSIBLE SIDE EFFECTS OF LENALIDOMIDE SPC®

### LENALIDOMIDE SPC® may cause serious side effects.

Serious skin reactions. Serious skin reactions can happen with LENALIDOMIDE SPC® and may cause death. Call your healthcare provider right away if you have any skin reaction while taking LENALIDOMIDE SPC®.

Tumor lysis syndrome. Metabolic complications that can occur during treatment of cancer and sometimes even without treatment. These complications are caused by the breakdown products of dying cancer cells and may include the following: changes to blood chemistry, high potassium, phosphorus, uric acid, and low calcium consequently leading to changes in kidney function, heart beat, seizures, and sometimes death.

Common side effects of LENALIDOMIDE SPC® are:

- diarrhea
- itching
- rash
- tiredness

These are not all the possible side effects of LENALIDOMIDE SPC®. Tell your healthcare provider about any side effect that bothers you or that does not go away.

## HOW SHOULD YOU TAKE LENALIDOMIDE SPC®?

Take LENALIDOMIDE SPC® exactly as prescribed and follow all the instructions of the LENALIDOMIDE SPC® REMS program

Swallow LENALIDOMIDE SPC® capsules whole with water 1 time a day.

Do not open, break, or chew your capsules

LENALIDOMIDE SPC may be taken with or without food

Take LENALIDOMIDE SPC® at about the same time each day

Do not open the LENALIDOMIDE SPC capsules or handle them any more than needed. If you touch a broken LENALIDOMIDE SPC capsule or the medicine in the capsule, wash the area of your body right away with soap and water

If you miss a dose of LENALIDOMIDE SPC and it has been less than 12 hours since your regular time, take it as soon as you remember. If it has been more than 12 hours, just skip your missed dose. Do not take 2 doses at the same time

If you take too much LENALIDOMIDE SPC, call your healthcare provider right away

Do not share LENALIDOMIDE SPC with other people. It may cause birth defects and other serious problems

## WANT TO KNOW MORE?

For more information about LENALIDOMIDE SPC® CALL SFDA / SPC

### SPC

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