



OMDEGZI (Lenalidomide)

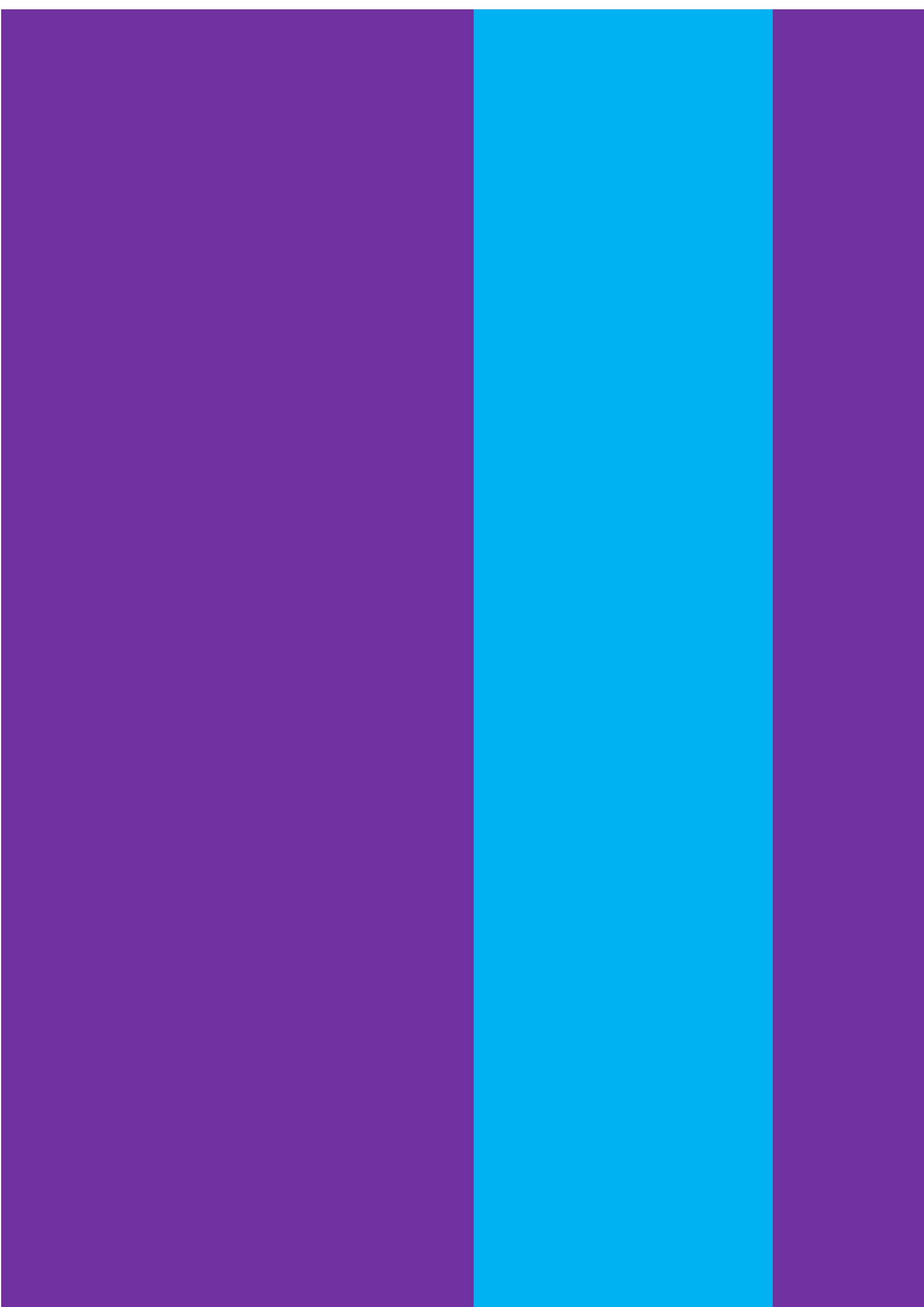
PATIENT GUIDE

**Important Risk Minimization
Information for Patients.**

November, 2025

Ver. no. 0001

This document has been reviewed and approved by The Saudi Food and Drug Authority (SFDA).



Topic	Page
Requirements for Females who are Able to Become Pregnant	5
Requirements for Females who are NOT able to Become Pregnant	7
Requirements for Male Patients	8
Special Warnings and Precautions	9
How should you take OMDGEZI?	9
Want to Know More?	10



Introducing

Your Doctor intends to prescribe OMDEGZI for you. OMDEGZI (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 OMDEGZI is taken during pregnancy it may cause birth defects or death to an unborn baby. To avoid fetal exposure, OMDEGZI[®] is available only under a special distribution program. The program is designed to ensure that OMDEGZI therapy is always prescribed and taken in the recommended way. Key features of the program: Only physicians registered with program can prescribe OMDEGZI. Only pharmacists/pharmacies registered with program can dispense OMDEGZI. Only patient who have been formally enrolled in the program can receive OMDEGZI. To enroll, patients must sign a “OMDEGZI Treatment Initiation Form”



IMPORTANT TO REMEMBER OMDEGZI may cause birth defects or death to unborn babies.



Special Requirements for Females who are Able to Become Pregnant

t

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 OMDEGZI treatment
- While taking OMDEGZI
- During any interruption in OMDEGZI treatment
- During the four-week period following the conclusion of your OMDEGZI treatment

Before starting treatment:

1. You must sign a “OMDEGZI Treatment Initiation Form”, agreeing not to become pregnant while taking OMDEGZI
2. You must use two reliable methods of birth control (contraception) at the same time 4 weeks before starting OMDEGZI 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

Contraceptive methods must include:

1. At least 1 highly effective method AND 1 additional effective barrier method used at the same time.
2. You must have a medically supervised pregnancy test done during your consultation with the doctor, when Lenalidomide 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
3. You must agree to not breastfeed or donate blood
4. You must agree to never share your Lenalidomide capsules
5. You must agree to return unused Lenalidomide capsules to your pharmacist

During treatment and dose interruptions:

1. You must continue to use two reliable methods of birth control (contraception) at the same time during treatment and during any interruption in Lenalidomide treatment
2. You must also undergo regular medically supervised pregnancy tests every four weeks during treatment
3. You must not breastfeed or donate blood
4. Never share your Lenalidomide 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 immediately
- ✓ Tell your doctor
- ✓ Have a pregnancy test

For four weeks after treatment:

1. You must continue to use two reliable methods of birth control (contraception) at the same time
2. You must not breastfeed or donate blood
3. Never share your Lenalidomide capsules
4. Return unused Lenalidomide capsules to your pharmacist
5. You must undergo a medically supervised pregnancy test 4 weeks after discontinuation of Lenalidomide 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).

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

Before starting treatment:

1. You must sign a "Lenalidomide Treatment Initiation Form", indicating that you are not pregnant and do not have the ability to have children and will follow all requirements within.
2. You must agree to not donate blood
3. You must agree to never share your Lenalidomide capsules
4. You must agree to return unused Lenalidomide capsules to your pharmacist

During treatment and during dose interruptions:

1. You must not donate blood
2. Never share your Lenalidomide capsules

For four weeks after treatment:

1. You must not donate blood
2. Return unused Lenalidomide capsules to your pharmacist

Requirements for Male Patients**Before starting treatment:**

Lenalidomide is present in semen. You must sign a "Lenalidomide 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 following requirements within including the following:

- o You must agree to not donate blood
- o You must agree to never share your Lenalidomide capsules
- o You must agree to return unused Lenalidomide capsules to your pharmacist

During treatment and during dose interruptions:

1. 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)
2. 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
3. You must not donate blood
4. Never share your Lenalidomide capsules

For four weeks after treatment:

1. 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)
2. 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
3. You must not donate blood
4. Never share your Lenalidomide capsules
5. Return unused Lenalidomide capsules to your pharmacist

Special Warnings and Precautions**Low white blood cells (neutropenia) and low platelets (thrombocytopenia).**

Lenalidomide 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, 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:

- a. shortness of breath
- b. chest pain
- c. arm or leg swelling

Possible side effects of Lenalidomide

Lenalidomide may cause serious side effects.

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

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 are:

diarrhea

itching

rash

tiredness

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

How should you take Lenalidomide?

Take Lenalidomide exactly as prescribed and follow all the instructions of the program. Swallow Lenalidomide capsules whole with water once a day. Do not break, chew, or open your capsules. Do not open the Lenalidomide capsules or handle them any more than needed. If you touch a broken Lenalidomide capsule or the medicine in the capsule, wash the area of your body with soap and water.

If you miss a dose of Lenalidomide, 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 or overdose, call your healthcare provider or poison control center right away.

Reporting of ADRs

The National Pharmacovigilance Centre (NPC)

Call Center: 19999

E-mail: npc.drug@sfda.gov.sa

Online: <https://ade.sfda.gov.sa>

Or

Alpha Pharma Drug Safety:

Tell: +966 11 293 1773 Ext: 111

Mobile: +966 53 040 8553 (24/7)

Alpha Pharma Industries, Al-Akaria 2nd, 4th floor, office No. 422, Olaya street, Al-Olaya district, Riyadh, Saudi Arabia.

Email: pv@alphapharma.com.sa

Website: <https://alphapharma.com.sa/>

