PREGNANCY PREVENTION PROGRAM

OMDEGZI (Lenalidomide)

Information for Healthcare Professionals

November,2025

Ver. no. 0001

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

Topic		Page no.
Introduction		3
The Pregnancy Prevention Programme		4
Reporting of Adverse Reactions		17
Alpha Pharma Drug Safety and Medical Information Contact Detalis		18
Additional Information (Appendices)	a) HCP Information Pack (Brochure)	19
	b) Education and counselling Checklist	19
	c) Treatment Initiation Form	23
	d) Dispense Authorization Form	27
	e) Prescription Authorization Form	30
	f) Pregnancy capture form	33

HCP Information guide
Information for Healthcare Professionals Prescribing or Dispensing Lenalidomid

Introduction

OMDEGZI (lenalidomide) is licensed for use in combination with dexamethasone for the treatment of patients with multiple myeloma who have received at least one prior therapy and Myelodysplastic syndromes (MDS) and Mantle cell lymphoma (MCL)
(Omdegzi) is a thalidomide analogue, a known human teratogenic substance that causes severe life-threatening birth defects. If Omdegzi is taken during pregnancy a teratogenic effect cannot be ruled out. Omdegzi is therefore contraindicated in pregnancy and in women of child-bearing potential unless the conditions of the Pregnancy Prevention Programme described in this pack are carried out.
It is a requirement of the Pregnancy Prevention Programme that all healthcare professionals ensure that they have read and understood this pack before prescribing or dispensing Omdegzi for ANY patient.

- The categorisation of patients based on sex and childbearing potential is set out in the algorithm available in this Healthcare Professional`s Information Guide, see section 6.0.
- All men and all women of childbearing potential should undergo, at treatment initiation, counselling regarding theneed to avoid pregnancy (this must be documented via a Risk Awareness Form)
- Patients should be capable of complying with the requirements of safe use of lenalidomide.
- Patients must be provided with the appropriate Patient Brochure, Risk Awareness Form and Patient Pocket Information Card.

In order to obtain lenalidomide, it is a requirement of the Pregnancy Prevention Programme that all healthcare professionals ensure that they have read and understood the Additional Risk Minimisation Materials before prescribing or dispensing lenalidomide for any patient.

For further information about the appropriate use and safety profile of Omdegzi please refer to the Summary of Product Characteristics (SPC) contained within this pack.

The Pack also includes:

- Prescription authorisation forms (which must be completed for each prescription of Omdegzi -see later)
- A pharmacy authorisation agreement (all pharmacies dispensing (Omdegzi) must be registered with the Company so that distribution to that pharmacy can be authorised - see later)
- Checklists and algorithms to assist minimisation of the principle risks of treatment

November,2025

Ver. no. 0001

- A patient information brochure and example informed consent form
- A pregnancy reporting form to assist urgent communication of information to the Alpha Pharma and the regulatory agencies of any instances of foetal exposure to (Omdegzi.)
- An example letter containing important risk minimisation information to communicate to the GPs of patients taking Omdegzi.
- Patient wallet cards carrying key information about the product and its safe use
- Adverse reaction report forms
- Further copies of this pack and the materials within it can be ordered from Alpha Pharma (contact details in Section 5) or by speaking to any Alpha Pharma representative.

The Pregnancy Prevention Programme (PPP)

The Pregnancy Prevention Programme (PPP) has the following mandatory elements:

- All healthcare professionals dispensing or prescribing lenalidomide must read the Lenalidomide Pregnancy Prevention Programme materials.
- All pharmacists who dispense lenalidomide must agree to implement risk minimization by registering with the Pregnancy Prevention Programme .
- If a registered third-party pharmacy is only dispensing lenalidomide, the pharmacy where the PAFs are being approved must also register with the Pregnancy Prevention Programme .
- Every prescription for lenalidomide must be accompanied by a PAF which can be completed by the prescriber and the pharmacist

A. Patient and healthcare professional education

All patients must sign an informed consent form confirming their awareness of the risks of treatment, particularly of the risks associated with foetal exposure and their agreement to adhere to the requirements of the programme.

All patients should be given a patient brochure to take home. The brochure has separate sections of information for women of child- bearing potential, women of non-childbearing potential and men.

All healthcare professionals involved in the prescribing or dispensing of lenalidomide must confirm that they have read this pack on the prescription authorisation form described below.

The Company is happy to provide further information and slide presentations on the PPP to any haematology department or pharmacy requesting it. Please contact the Medical Information and Drug Safety Department of Alpha Pharma.

B. Therapeutic management advice to avoid foetal exposure

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 every 4 weeks, including 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.

Additional precautions

Patients should be instructed never to give this medicinal product to another person and to return any unused capsules to their pharmacist at the end of treatment. Patients should not donate blood during therapy or for 1 week following discontinuation of lenalidomide.

Educational materials, prescribing and dispensing restrictions

In order to assist patients in avoiding foetal exposure to lenalidomide, the Marketing Authorisation Holder will provide educational material to health care professionals to reinforce the warnings about the expected teratogenicity of lenalidomide, to provide advice on contraception before therapy is started, and to provide guidance on the need for pregnancy testing. The prescriber must inform male and female patients about the expected teratogenic risk and the strict pregnancy prevention measures as specified in the Pregnancy Prevention Programme and provide patients with appropriate patient educational brochure, patient card and/or equivalent tool in accordance to the national implemented patient card system. A national controlled distribution system has been implemented in collaboration with each National Competent Authority.

The controlled distribution system consists of:

- Important Safety Information for Healthcare Professionals Materials.
- Pregnancy outcome form (Event-Specific Questionnaire for HCP)
- Important Safety Information for Patients Materials.
- patient card for prescribing and/or dispensing controls .
- Risk Awareness Forms for counselling the patient to ensure the patient is fully informed about the safe use of lenalidomide:
    - Woman of Childbearing Potential Risk Awareness Form.
    - Women of Non-Childbearing Potential Risk Awareness Form.
    - Male Risk Awareness Form.

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 and following a medically supervised negative pregnancy test result.

Women of non-childbearing potential

Women in the following groups are considered NOT to have child-bearing potential and do not need to undergo pregnancy testing or receive contraceptive advice.

- Age ≥50 years and naturally amenorrhoeaic for ≥ 1 year. Please note amenorrhoea following cancer therapy does not rule out child-bearing potential
- Premature or during breast-feeding ovarian failure confirmed by a specialist gynaecologist
- Previous bilateral salpingo-oophorectomy or hysterectomy
- XV genotype, Turner syndrome, uterine agenesis

Amenorrhoea following cancer therapy or during breastfeeding does not rule out childbearing potential.

A female patient is considered to have childbearing potential unless she meets at least one of the above criteria.

Treating physicians are advised to refer their patient for a gynaecological opinion if at all unsure as to whether a woman meets the criteria for being of non-childbearing potential.

Women of child-bearing potential

- Pregnant
- A woman who is able to become pregnant, even if not planning to become pregnant, unless all of the conditions of the Pregnancy Prevention Programme are met.

In view of the expected teratogenic risk of lenalidomide, foetal exposure must be avoided.

Women of child-bearing potential (even if they have amenorrhoea) must:

- Use at least one effective method of contraception for 4 weeks before therapy, during therapy, and until at least 4 weeks after lenalidomide therapy.
- two reliable methods after (Omdegzi) therapy, and even in case of dose interruption.
- Do not prescribe Omdegzi during pregnancy, as it is expected to cause harm to the fetus.
- Advise female patients of childbearing potential to avoid becoming pregnant while receiving Omdegzi treatment.
- Therefore, women of childbearing potential must use effective contraception during treatment with Omdegzi.
- If the woman of childbearing potential becomes pregnant during treatment with(Omdegzi).Treatment with (Omdegzi) should be stopped .
- Patients should be advised to inform the healthcare professional prescribing the contraception about the lenalidomide treatment.
- Patients should be advised to inform you if a change or stop of the method of contraception is needed.

- Or Commit to absolute and continuous abstinence and
- Have a medically supervised negative pregnancy test (with a minimum sensitivity of 25 IU/ml) once she has been established on contraception for 4 weeks, at 4 weekly intervals during therapy and 4 weeks after the end of therapy (unless confirmed tubal sterilization)

There must be no more than **3 days** between the dates of the last negative pregnancy test and the last prescription. Best practice is for the pregnancy test, prescribing and dispensing to take place on the same day.
If not established on effective contraception, the patient must be referred to an appropriately trained healthcare 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)

Reminder:
TREATMENT FOR A WOMAN OF CHILDBEARING POTENTIAL CANNOT START UNTIL THE PATIENT IS
ESTABLISHED ON AT LEAST ONE EFFECTIVE METHOD OF CONTRACEPTION FOR AT LEAST 4 WEEKS OR COMMITS TO ABSOLUTE AND CONTINUOUS ABSTINENCE AND PREGNANCY TEST IS NEGATIVE.

Your patient should be advised that if a pregnancy does occur whilst she is receiving lenalidomide, she must stop treatment immediately and immediately inform her prescriber

Men

In view of the potential teratogenic risk of (Omdegzi), foetal exposure should be avoided. It is not currently known if (Omdegzi) is present in semen therefore:

- Male patients should use condoms throughout the duration of treatment, during dose interruption and for one week .Inform your patient which are the effective contraceptive methods that his female partner can use.after cessation of treatment if their wife is of child-bearing potential and has no contraception even if the male patient has undergone vasectomy.
- Male patients should be instructed that if their partner becomes pregnant whilst taking (Omdegzi) or shortly after he has stopped he should inform his treating doctor immediately.

November,2025

Ver. no. 0001

C. A distribution control system

In order to ensure that the actions to minimise the risk of foetal exposure are carried out for all patients, dispensing of (Omdegzi) will only be allowed from pharmacies registered with Alpha Pharma. The Company will not authorise supply of (Omdegzi) to pharmacies not registered with the Company.

In order to be registered the chief pharmacist or appointed deputy of the institution wishing to dispense must agree to implement and audit the use of a Prescription Authorisation Form (standard agreement letter and form enclosed with this pack).

The contents of the Prescription Authorisation Form can be incorporated into the institution's standard prescription or it can be used separately to the prescription but MUST accompany it.

The Prescription Authorisation Form asks the prescribing physician to confirm:

- Whether the patient is male or female
- If female, the patient's child-bearing potential
- If of child-bearing potential that adequate contraception is in place and the date of the last negative pregnancy test, which must be within the 3 DAYS prior to the date of the prescription
- If male that counselling regarding the use of condoms has taken place
- That informed consent has been completed by the patient
- That the physician has read and understands the contents of this pack
- The Prescription Authorisation Form asks the dispensing pharmacist to confirm
- That the prescription and Prescription Authorization Forms have been completed in full
- That dispensing is taking place 7 DAYS OR LESS from the date of prescribing
- That the pharmacist has read and understood the contents of this pack

In addition to these measures the length of any prescription must be limited to one month though the prescription may be renewed up to 15 days prior to completion of the last cycle (i.e. not to be re-supplied within 13 days of any previous prescription).

D. Follow-up assessment of the effectiveness of the Programme

Alpha Pharma are committed to assessing and developing the effectiveness of this programme and will perform audits annually to gain feedback. The results of audit will be discussed with SFDA.

Pharmacy registration with the Company to dispense (Omdegzi) requires that pharmacies perform an annual internal audit of the process. The Company will supply an audit tool to assist this and is required by Saudi Food and Drug Authority (SFDA) to report the collated results of such an audit.

In the event of pregnancy whilst on treatment with Omdegzi

- Stop treatment
- Refer patient to a physician specialised or experienced in teratology for evaluation and advice, Notify Alpha Pharma immediately by contacting the Alpha Pharma Drug Safety Department (contact details in section 5) and completing the Pregnancy Capture Form included in this pack. Alpha Pharma will wish to follow-up with you the progress of all pregnancies.

November,2025

Ver. no. 0001

- Report the event to the SFDA using the following contact:

  - The National Pharmacovigilance Centre (NPC):
  - E-mail: npc.drug@sfda.gov.sa
  - Online: https://ade.sfda.gov.sa
  - 19999

Advice to all Patients

Points to Consider for Handling the Medicinal Product: For Healthcare Professionals and Caregivers :

- Do not share the medicinal product with anyone else, even if they have similar symptoms. Store them safely so that no-one else can take them by accident and keep them out of the reach of children. Keep the blisters with the capsules in the original pack.
- Capsules can occasionally become damaged when pressing them out of the blister, especially when the pressure is put onto the middle of the capsule. Capsules should not be pressed out of the blister by putting pressure on the middle. The pressure should be located at one site only, which reduces the risk of the capsule deforming or breaking (see figure below).
- Healthcare professionals and caregivers should wear disposable gloves when handling the blister or capsule. Remove gloves carefully to prevent skin exposure. Place in a sealable plastic polyethylene bag. Dispose of any unused medication in accordance with local requirements. 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.

When handling the medicinal product use the following precautions to prevent potential exposure if you are a healthcare professional or caregiver:

• If you are a woman who is pregnant or suspect that you may be pregnant, you should not handle the blister or capsule
• Wear disposable gloves when handling product and/or packaging (i.e. blister or capsule)

• Use proper technique when removing gloves to prevent potential skin exposure (see below)
• Place gloves in sealable plastic polyethylene bag and dispose according to local requirements
• Wash hands thoroughly with soap and water after removing gloves.
• Patients should be advised never to give the medicinal product to another person.

If a drug product package appears visibly damaged, use the following extra precautions to prevent Exposure:
• If outer carton is visibly damaged – Do Not Open
• If blister strips are damaged or leaking or capsules are noted to be damaged or leaking – Close Outer Carton Immediately

November,2025

Ver. no. 0001

• Place the product inside a sealable plastic polyethylene bag
• Return unused pack to the pharmacist for safe disposal as soon as possible.

If product is released or spilled, take proper precautions to minimize exposure by using appropriate personal protection:
• If capsules are crushed or broken, dust containing drug substance may be released. Avoid dispersing the powder and avoid breathing on or inhaling the powder
• Wear disposable gloves to clean up the powder
• Place a damp cloth or towel over the powder area to minimise entry of powder into the air. Add excess liquid to allow the material to enter solution. After handling, clean the area thoroughly with soap and water and dry it
• Place all contaminated materials including damp cloth or towel and the gloves into a sealable polyethylene plastic bag. Dispose of it in accordance to local requirements for medicinal products
• Wash your hands thoroughly with soap and water after removing the gloves
• Please report to the relevant MAH immediately using the contact details available in the Pregnancy Prevention Programme (PPP).

If the contents of the capsule are attached to the skin or mucous membranes:
• If you touch the drug powder, please wash exposed area thoroughly with running water and soap
• If the powder gets in contact with your eye, if worn and if easy to do, remove contact lenses and discard them. Immediately flush eyes with copious quantities of water for at least 15 minutes. If irritation occurs, please contact an ophthalmologist.

Proper Technique for Removing Gloves:

1. Grasp outside edge near wrist
2. Peel away from hand, turning glove inside-out
3. Hold in opposite gloved hand
4. Slide ungloved finger under the wrist of the remaining glove, being careful not to touch the outside of the glove
5. Peel off from inside, creating a bag for both gloves.
6. Discard in appropriate container
7. Wash your hands with soap and water thoroughly.

Blood Donation

Patients should not donate blood during treatment (including dose interruptions) and for at least 7 days after cessation of treatment with lenalidomide..

Prescribing and Dispensing Lenalidomide:

Lenalidomide will only be available under a special distribution program. The aims of this program are to:

• Ensure that use and distribution of Lenalidomide are closely monitored and well controlled

a. Only prescribers registered with program can prescribe Lenalidomide
b. Patients must enroll in the program to receive Lenalidomide
c. Only pharmacists/pharmacies registered with program can dispense Lenalidomide

• Ensure that patients taking Lenalidomide are fully informed about their treatment and –most importantly – that they take all necessary steps to avoid exposing unborn babies to Lenalidomide

a. Prescribers must inform patients about the likely benefits and potential risks of Lenalidomide therapy, and properly explain how potential risks can be avoided or minimized
b. Patients must formally agree to fully comply with the requirements of the program, by signing a “Lenalidomide Treatment Initiation Form”
c. Females of Child bearing Potential (FCBP) are mandated to perform pregnancy tests before taking Lenalidomide and later on with every single dispense (every 4 weeks), including 4 weeks after the end of treatment, except in the case of confirmed tubal sterilisation. d. Prescribers must provide patients a “Lenalidomide patient brochure”

Responsibilities for registered participants

Prescribers:

1. All prescribers MUST be registered with Program to prescribe Lenalidomide

a. To register, prescribers must complete a “Lenalidomide Prescriber Registration Form” after receiving this “Lenalidomide Healthcare Professional Information Pack”
b. Complete and sign the “Lenalidomide Prescriber Registration Form” and provide.
c. For further information about the registration process please contact your local medical representative.

2. Prescriber MUST agree to the following:

a) Provide counseling to each patient:
- ♣ Why it is important not to expose unborn babies to Lenalidomide and what patients can do to prevent such exposure
- ♣ What registered patients responsibilities are in this regard
- ♣ Advise all patients on Lenalidomide not to donate blood

♣ Advise all male patients not to donate semen or sperm when taking
♣ Lenalidomide advise all patients who are or might be engaged in any sexual activity to adhere to the effective

contraception methods
♣Advise all FCBP patients not to breast feed if Lenalidomide therapy was initiated post-partum
♣ Advise all patients not to share Lenalidomide
♣ Return unused Lenalidomide to the pharmacist
♣ On the likely benefits and possible side effects of Lenalidomide treatment
- o How to recognize potentially serious side effects
- o How to minimize the risk of developing serious side effects
- o What to do if symptoms of potentially serious side effects develop

b) Prescribe no more than a 4-week (28 day) supply of Lenalidomide per prescription for females of childbearing potential, or a maximum of 12-week (84-day) supply for all other patients

c) Provide each patient with the "Lenalidomide Patient Brochure "

d) Enroll each patient by submitting a completed and signed "Lenalidomide Treatment Initiation Form" for each new patient being prescribed Lenalidomide. This form must be completed by both the prescriber and the patient. The "Lenalidomide Treatment Initiation Form" is a written confirmation that the patient has received and understood information on the safe use of Lenalidomide. This form is to be completed at initiation of treatment for the first time or after there has been a change in the patient's risk category (e.g. Female of childbearing potential changes to female not of childbearing potential).

e) Send the "Lenalidomide Treatment Initiation Form" e.g. by email.

f) Retain a copy of the "Lenalidomide Treatment Initiation Form" in the patient's file

g) Then register the patient and forward a "Patient Registration Confirmation Letter" with a "Unique Patient Identification Number" (UPIN) to the prescriber. The UPIN must be written on each new "Lenalidomide Prescription Authorization Form", which must accompany each prescription for that particular patient. The "Lenalidomide Prescription Authorization Form" shows:

- Patient was counseled on safe use of Lenalidomide
- Patient risk category (female of childbearing potential; female NOT of childbearing potential; male)
- Pregnancy test date and result for female of childbearing potential (Prescriptions must be dispensed within a maximum of 7 days after the last negative pregnancy test date)
- Dosing prescribed
- Milligram strength and number of capsules to be dispensed

h) Provide the patient with a completed and signed "Lenalidomide Prescription Authorization Form" with each Lenalidomide prescription. The patient must present this form to the pharmacy, along with his prescription, or the prescriber may send the "Lenalidomide Prescription Authorization Form" with each prescription prescription to the pharmacy.

i) Adhere to guidelines when writing a prescription for Lenalidomide

Patients:

a. Patients must be enrolled in the program to receive Lenalidomide

1. Each patient (or his/her parent, legal guardian or authorized representative) must complete and sign the "Lenalidomide Treatment Initiation Form"
2. Patients must present the "Lenalidomide Prescription Authorization Form" to the pharmacy, along with their prescription or the prescriber may send the "Lenalidomide Prescription Authorization Form" and the Lenalidomide prescription to the pharmacy

b. Patients must agree to comply with all requirements of the program

1. Each patient must take all necessary steps to avoid exposing an unborn baby to Lenalidomide

Pharmacists:

a. Pharmacies must be registered with Program in order to dispense Lenalidomide

1. To register, pharmacies must complete and sign a "Lenalidomide Pharmacy RegistrationForm" after receiving this "Lenalidomide Healthcare Professional Information Pack" and sendthe completed form to Biologix

2. Biologix will approve dispenses and authorize shipments to the registered pharmacy

3. For further information about the registration process please contact Tel XXXX or your local medical representative

b. Registered pharmacists MUST agree to do the following:

1. Obtain a Lenalidomide prescription and the "Lenalidomide Prescription Authorization Form" and check the "Lenalidomide Prescription Authorization form" for completeness.

2. Provide counseling to each patient and fill the "Education and Counseling Check list used by the Registered Pharmacy".

3. Send the signed "Lenalidomide Prescription Authorization Form" and "Education and Counseling Check list" e.g. by email. 4. Dispense to a patient Lenalidomide as per approval sent by fax to the pharmacy

5. Dispense no more than a 4-week (28-day) supply of Lenalidomide for FCBP and up to a maximum of 12-week (84-day) supply for all other patient risk categories provided it was so approved.

6. A new prescription is required for further dispensing.

7. For subsequent prescriptions, verify there are 7 days or less since the last pregnancy test occurred.

8. For subsequent prescriptions, verify there are 7 days or less remaining of the 28-day cycles on the existing prescription.

What registered prescribers must do before prescribing Lenalidomide according to patient risk categories

The Program segments Lenalidomide patients in different risk categories according to their childbearing potential

1. Female of childbearing potential
   ♣ Females who do not meet the below definition of Female NOT of childbearing potential should be classified as FCBP.

2. Female NOT of childbearing potential
   ♣ Females 50 years old and naturally amenorrhoeic for 1 or 2 years
      o Amenorrhoea following cancer therapy or during breast-feeding does not does not rule out childbearing potential

   ♣ Females that have premature ovarian failure confirmed by a gynecologist
   ♣ Females that have not begun menstruation
   ♣ Females with bilateral salpingo-oophorectomy or hysterectomy
   ♣ Females with XY genotype, Turner's syndrome or uterine agenesis

3. Male
   ♣ To minimize the risk of a pregnancy occurring under the treatment of Lenalidomide there are different requirements for each of these patient's risk categories.

Requirements for females of childbearing potential (FCBP)

• Pregnancy testing

To confirm absence of a pregnancy, FCBP must have a medically supervised negative pregnancy test with a minimum sensitivity of 50 mlU/ml before starting Lenalidomide.

• A medically supervised pregnancy test should be performed during the consultation, when Lenalidomide is prescribed, or in the 7 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 that the FCBP patient is not pregnant when she starts treatment with Lenalidomide.

• During treatment, a medically supervised pregnancy test should be repeated every 4 weeks, including 4 weeks after the end of treatment, except in the case of confirmed tubal sterilisation.

• The prescriber documents the date and result of each pregnancy test on the "Lenalidomide Prescription Authorization Form".

1. . Contraception requirements for females of childbearing potential

• MUST be established on effective contraception for at least 4 weeks before initiating Lenalidomide therapy

• Use simultaneously two reliable methods of contraception simultaneously for 4 weeks before Lenalidomide therapy, during therapy, during dose interruption and until 4 weeks after therapy

There must be no more than 7 days between the dates of the last negative pregnancy test and the dispensing of Lenalidomide. Ideally, pregnancy testing, issuing a prescription and dispensing should occur on the same day if not established on effective contraception, the patient should be referred to an appropriately trained Healthcare Professional for contraceptive advice before initiating Lenalidomide treatment.

2.Examples of effective methods of contraception

a) Highly effective methods

o Intra Uterine Device (IUD)
o Hormonal (hormonal implants, levonorgestrel-releasing intrauterine system (IUS), medroxyprogesterone acetate depot injections, ovulation inhibitory progesterone-only pills e.g. desogestrel)
o Tubal ligation o Partner's vasectomy

b) Effective methods

o Male condom
o Diaphragm
o Cervical cap

Contraceptive methods must include: At least 1 highly effective method AND 1 additional effective barrier method used at the same time.
Hormonal contraception should be initiated 4 weeks before starting Lenalidomide treatment.
Because of the increased risk of venous thromboembolism in patients with multiple myeloma taking Lenalidomide and dexamethasone, combined oral contraceptive pills are not recommended.
Advise patient that if a pregnancy does occur whilst she is receiving Lenalidomide, she must stop treatment immediately and inform her doctor immediately.

3.In the event of pregnancy whilst on treatment with Lenalidomide

♣ Stop treatment with Lenalidomide
♣ Refer the patient to a Gynecologist/Obstetrician experienced in reproductive toxicity

Requirements for females not of childbearing potential

♣ Provide counseling as described in above section (Prescribers)
♣ Treating Physicians are advised to refer their patient for a gynecological opinion if at all unsure as to whether a woman meets the criteria for being of a female NOT of childbearing potential

Requirements for males

Traces of Lenalidomide are present in semen, therefore:

- Male patients should practice complete abstinence or use condoms during sexual intercourse with a pregnant female or a female of childbearing potential throughout the duration of treatment, during dose interruption and for 4 weeks after cessation of treatment if their partner is not established on suitable contraception (even if the male patient has undergone vasectomy)

- Male patients must not donate semen or sperm during therapy including dose interruptions and for 4 weeks following the discontinuation of Lenalidomide Version.2 October 2024 Male patients should be instructed that if their partner becomes pregnant whilst they take Lenalidomide or shortly after the patient stopped Lenalidomide treatment, he should inform his doctor immediately. Inform your patient which are the effective contraceptive methods that his female partner can use.

4. Writing subsequent Lenalidomide prescriptions

   When a patient requires a new prescription, simply record the UPIN on the "Lenalidomide Prescription Authorization Form" which should accompany the Lenalidomide prescription

5. Reporting of Adverse Events

   The safe use of Lenalidomide is of paramount importance. As part of the ongoing safety monitoring, wish to learn of Adverse Events that have occurred during the use of Lenalidomide

6. For ADR reporting

Adverse Reaction report forms are included in this Healthcare Professional Pack and should be forwarded to Alpha Pharma at the address below. They should also be reported to the SFDA using the following:

The National Pharmacovigilance Centre Saudi Food and Drug Authority

Call Center: 19999

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

Website: https://ade.sfda.gov.sa/

Alpha Pharma contact details:

Tell: +966 11 293 1773 Ext: 111

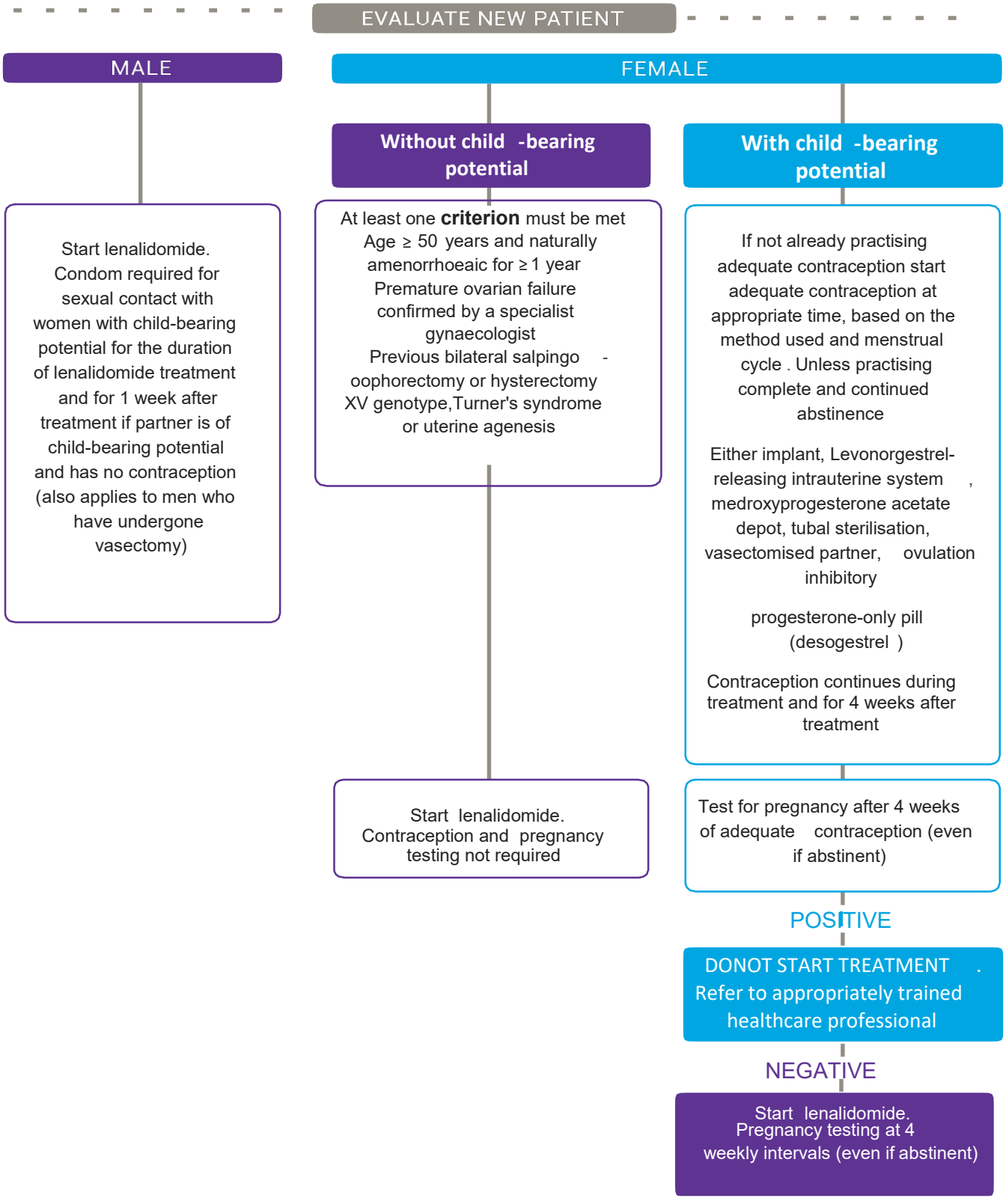
Mobile: +966 53 040 8553 (24/7)

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

Email: pv@alphapharma.com.sa

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

Algorithm For Implementation of PPP



November,2025

Ver. no. 0001

Warnings And Precautions

Programme in female patients

The conditions of the Pregnancy Prevention Programme must be fulfilled for all patients unless it has been proven that the patient cannot become pregnant.

Criteria for clarification of the potential for pregnancy.

A female patient or the female partner of a male patient is classified as having childbearing potential unless she fulfils at least one of the following conditions:

- Age ≥50 years and naturally amenorrhoeic for ≥1 or 2 years *
- Premature ovarian failure confirmed by a gynaecologist
- Female that has not begun menstruation
- Previous bilateral salpingo-oophorectomy, or hysterectomy
- XV genotype, Turner's syndrome, uterine agenesis

Amenorrhoea following cancer therapy does not rule out childbearing potential

Reporting Of Adverse Reactions

The safe use of (Omdegzi) is of paramount importance. As part of the ongoing safety monitoring Alpha Pharma wishes to learn of Adverse Reactions that have occurred during the use of (Omdegzi).

Adverse Reaction report forms are included in this Healthcare Professional Pack and should be forwarded to the Alpha Pharma Drug Safety Department at the address below. They should also be reported to the SFDA using the following:

The National Pharmacovigilance Centre (NPC):

Call Center: 19999
E-mail: npc.drug@sfda.gov.sa
Website: https://ade.sfda.gov.sa/

November,2025

Ver. no. 0001

Alpha Pharma Drug Safety And Medical Information Contact Details

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 steet,Al-Olaya district, Riyadh, Saudi Arabia.

Email: pv@alphapharma.com.sa

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

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November,2025

Ver. no. 0001

Omdegzi Risk Minimization Measures (RMM)

Program Education And Prescribing Safety

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

November,2025

Ver. no. 0001

Omdegzi Risk Minimization Measures (RMM)

PROGRAM EDUCATION AND PRESCRIBING SAFETY

Authorization No.: ……..

Confirmation No.: ……...

Confirmation Date: ……

Pharmacy Name: ……....

Pharmacy Address: ……

Counselor Name: ……....

Work Phone: ……....

Ext.: ……....

Patient Name: ……....

Date of Birth: ……....

Risk Category: ……....

Checklist for female patients of reproductive potential

I will make sure that patients are aware that they will receive the Medication Guide along with their prescription	

I COUNSELED ADULTS AND CHILDREN ON

Potential embryo-fetal toxicity	
Not taking (Omdegzi) if pregnant or breastfeeding	
Using at the same time at least l highly effective method-tubal ligation, IUD, hormonal (birth control pills, hormonal patches, injections, vaginal rings, or implants), or partner's vasectomy-and at least l additional effective method of birth control-male latex or synthetic condom, diaphragm, or cervical cap-every time they have sex with a male, or abstaining from sex with a male	
Unacceptable methods of birth control are progesterone-only “mini-pills”, IUD Progesterone T, female condoms, natural family planning (rhythm method) or breastfeeding, fertility awareness, withdrawal, and cervical shield (a cervical shield should not be confused with a cervical cap, which is an effective secondary form of contraception)	
Continuing to use at the same time at least 1 highly effective method and at least 1 additional effective method of birth control beginning at least 4 weeks before taking Omdegzi while taking Omdegzi dose during	

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November,2025

Ver. no. 0001

interruptions, and for at least 4 weeks after stopping Omdegzi every time they have sex with a male, or abstaining from sex with a male	
Obtaining a pregnancy test-performed by their healthcare provider-weekly during the first 4 weeks of use. Thereafter, pregnancy testing should be repeated every 4 weeks during the rest of their treatment in females with regular menstrual cycles or no cycle at all. If menstrual cycles are irregular, the pregnancy testing should occur every 2-weeks	
The need to stop taking Omdegzi right away in the event of becoming pregnant, or if they think for any reason they may be pregnant, and to call their healthcare provider immediately	
Possible side effects include neutropenia, thrombocytopenia, deep vein thrombosis, and pulmonary embolism as well as risk of myocardial infarction and stroke	
The need for del 5q MDS patients to schedule a blood test every week for the first 8 weeks and monthly thereafter to monitor blood counts while taking Omdegzi	
Not sharing Omdegzi capsules with anyone-especially with females who can get pregnant	
Not donating blood while taking Omdegzi (including dose interruptions) and for 4 weeks after stopping Omdegzi	
Not breaking, chewing, or opening Omdegzi capsules	
Instructions on Omdegzi dose and administration	
Milligram (mg) Strength:	Number of Capsules Dispensed:

Checklist for female patients not of reproductive potential (natural menopause for at least 24 consecutive months, a hysterectomy, and/or bilateral oophorectomy)

I will make sure that patients are aware that they will receive the Medication Guide along with their prescription	

I COUNSELED ADULTS AND CHILDREN ON

Possible side effects include neutropenia, thrombocytopenia, deep vein thrombosis, and pulmonary embolism as well as risk of myocardial infarction and stroke	
The need for del 5q MDS patients to schedule a blood test every week for the first 8 weeks and monthly thereafter to monitor blood counts while taking OMDEGZI	
Not sharing OMDEGZI capsules with anyone—especially with females who can get pregnant	
Not donating blood while taking OMDEGZI (including dose interruptions) and for 4 weeks after stopping OMDEGZI	
Not breaking, chewing, or opening OMDEGZI capsules	
Instructions on OMDEGZI dose and administration	
Milligram (mg) Strength:	Number of Capsules Dispensed:

Checklist for male patients

I will make sure that patients are aware that they will receive the Medication Guide along with their prescription	

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Ver. no. 0001

I COUNSELED ADULTS AND CHILDREN ON

Potential embryo-fetal toxicity and contraception (wearing a latex or synthetic condom every time when engaging in sexual intercourse with a female who can get pregnant, even if the patient has had a successful vasectomy)	
Female partners of males taking (Omdegzi) must call their healthcare provider right away if they get pregnant	
Possible side effects include neutropenia, thrombocytopenia, deep vein thrombosis, and pulmonary embolism as well as risk of myocardial infarction and stroke	
The need for del 5q MDS patients to schedule a blood test every week for the first 8 weeks and monthly thereafter to monitor blood counts while taking Omdegzi	
Not sharing Omdegzi capsules with anyone-especially with females who can get pregnant	
Not donating blood or sperm while taking Omdegzi (including dose interruptions) and for 4 weeks after stopping Omdegzi	
Not breaking, chewing, or opening Omdegzi capsules	
Instructions on Omdegzi dose and administration	
Milligram (mg) Strength:	Number of Capsules Dispensed:

MALE CHILDREN (<18 YEARS OF AGE)

Parent or legal guardian must have read the (Omdegzi) education material and agreed to ensure compliance	

All boxes and spaces must be marked or filled in during counseling with the patient for every prescription.

Counselor Signature: **Date:**

……..

Tell: +966 11 293 1773 Ext: 111 Alpha Pharma Industries, Al-Akaria 2nd, 4th floor, office No. 422, Olaya steet,Al-Olaya district, Riyadh, Saudi Arabia. **Please see full Prescribing Information, including Boxed Warnings, Contraindications, Warnings And Precautions, and Adverse Reactions, enclosed**	The National Pharmacovigilance Centre (NPC) Call Center: 19999 E-mail: npc.drug@sfda.gov.sa Online: https://ade.sfda.gov.sa

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Ver. no. 0001

Treatment Initiation Form

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November,2025

Ver. no. 0001

Treatment Initiation Form

Warning: Severe life-threatening birth defects. If Omdegzi is taken during pregnancy it can cause severe birth defects or death to an unborn baby.

Patient Details

Patient First Name:			
Patient Last Name:			
Date of Birth:		**Counselling Date:**	

Pregnancy Prevention Referral

Pregnancy prevention referral required				Y or N
Pregnancy prevention referral made		DD	MM	YYYY
Pregnancy prevention consultation conducted on		DD	MM	YYYY

Pregnancy Prevention

The patient has been established on one of the following for at least 4 weeks	Tick
Implant Tick	Tick
Levonorgestrel-releasing intrauterine system (IUS)	Tick
Medroxyprogesterone acetate depot	Tick
Tubal sterilization	Tick
Sexual intercourse with a vasectomised male partner only; vasectomy must be confirmed by two negative semen analyses	Tick
Ovulation inhibitory progesterone-only pills (i.e. desogestrel)	Tick
Committed to complete and absolute abstinence	Tick

Pregnancy Test

Pregnancy test date:	DD	MM	YYYY	**Result:**	Positive/Negative

Omdegzi treatment cannot start until the patient has been established on effective method of pregnancy prevention for 4 weeks, or commits to complete and continuous abstinence, and obtains a negative pregnancy test

Prescriber Confirmation

I have fully explained to the patient named above the nature, purpose and risks of the treatment associated with (Omdegzi) especially the risks to women of childbearing potential.

Prescriber First Name :					
Prescriber Last Name:					
Prescriber Signature:		**Date:**	DD	MM	YYYY

Patient: please read thoroughly and initial the adjacent box if you agree with the statement

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November,2025

Ver. no. 0001

I understand that severe birth defects can occur with the use of thalidomide. I have been warned by my doctor that any unborn baby has a high risk of birth defects and could even die if a woman is pregnant or becomes pregnant while taking (Omdegzi)	Patient initials
I understand that I must not take lenalidomide if I am pregnant or plan to become pregnant	Patient initials
I understand that I must use 2 effective method of pregnancy prevention without interruption, 4 weeks before starting treatment, throughout the entire duration of treatment, and 4 weeks after the end of treatment.	Patient initials
I understand that if I need to change or stop my method of pregnancy prevention I will discuss this first with the physician prescribing my pregnancy prevention method the physician prescribing my (Omdegzi)	Patient initials
I understand that before starting (Omdegzi) treatment I must have a pregnancy test.	Patient initials
I will then have a pregnancy test every 4 weeks during treatment, and a final test 4 week after the end of treatment	Patient initials
I understand that I must immediately stop taking (Omdegzi) and inform my doctor if I become pregnant while taking this drug; or if I miss my menstrual period or experience any unusual menstrual bleeding; or think FOR ANY REASON that I may be pregnant	Patient initials
I understand that (Omdegzi) will be prescribed ONLY for me. I must not share it with ANYONE	Patient initials
I have read the Omdegzi patient booklet and understand the contents, including the information about other possible health problems (side effects) from (Omdegzi)	Patient initials
I know that I cannot donate blood while taking (Omdegzi) or for 1 week after stopping treatment	Patient initials
I understand that I must return any unused (Omdegzi) to my pharmacy at the end of my treatment	Patient initials
I understand that I must provide a copy of this form to my pharmacy prior to obtaining my first prescription	Patient initials

Patient Confirmation

I confirm that I understand and will comply with the requirements of the Omdegzi Pregnancy Prevention Programme, and I agree that my doctor can initiate my treatment with Omdegzi

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November,2025

Ver. no. 0001

Prescriber Signature:		Date:	DD	MM	YYYY

This form based on the brand

يرجى قراءة المربع المجاور بالكامل ووضع علامة ✓ اذا كنت توافق

اتفهم أن هناك عيوب خلقية شديدة يمكن أن تحدث للجنين عند استخدام الليناليدوميد خلال فتره الحمل وقد تم تحذيري من قبل الطبيب الخاص بي بأن أي طفل لم يولد بعد فهو عرضة لمخاطر كبيرة من العيوب والتشوهات الخلقية ويمكن ايضاً أن يموت الجنين إذا كانت المرأة حامل أو اصبحت حاملاً أثناء تناول أوموديجزي	
أتفهم أنني يجب أن لا أتناول الليناليدوميد إذا كنت حامل أو أخطط للحمل.	
اتفهم أنه لا بد لي من استخدام طريقتين فعالة للوقاية من الحمل دون انقطاع 4 , أسابيع قبل بدء العلاج، طوال مدة العلاج، و 4 أسابيع بعد نهاية العلاج.	
أتفهم أنني إذا كنت بحاجة إلى تغيير أو إيقاف طرق منع الحمل ، فسيتم اولاً مناقشتها مع: • الطبيب الذي وصف لي طريقة الوقاية من الحمل. • الطبيب الذي وصف أوموديجزي	
اتفهم أنه قبل البدء في استخدام علاج أوموديجزي يجب أن أجري اختباراً للحمل.	
سوف أجري اختبار الحمل كل 4 أسابيع أثناء فترة العلاج ، واختبار نهائي بعد 4 أسابيع من نهاية استخدام العلاج	
اتفهم أنه يجب علي التوقف عن تناول ليناليدوميد فوراً وإبلاغ طبيبي إذا حصل حمل أثناء تناول الدواء , أو إذا تأخرأو عدم إنتظام في فترة الحيض فترة الحيض أو تعرضت لنزيف غير طبيعي , أو الاعتقاد لأي سبب من الأسباب أنني قد اكون حاملا.	
اتفهم أن أوموديجزي سوف يتم وصفه لي فقط وعليه يجب أن لا أشاركه مع أي شخص اخر.	
لقد قرأت النشرة الداخلية للمريض الخاصة بمستحضر أوموديجزي وفهمت محتوياتها ، بما في ذلك المعلومات حول المشاكل الصحية المحتملة الأخرى(الآثار الجانبية)	
أعلم أنه لا يمكنني التبرع بالدم أثناء تناول أوموديجزي ، كذلك لمدة ٤ أسابيع من بعد التوقف عن استخدام العلاج	
اتفهم انه عند الانتهاء من العلاج يجب عليّ أن أعيد أي كمية من أوموديجزي الغير مستخدمة إلى صيدلية المستشفى التي تم صرف الوصفه منها.	
أتفهم أنه يجب عليّ تقديم نسخة من هذا النموذج إلى الصيدلية قبل الحصول على أول وصفة	

اقرار المريض

انا أقر أنه يمكن لطبيبي البدأ بإستخدام أوموديجزي لعلاجي ، و أؤكد أني اتفهم و موافق على متطلبات برنامج أوموديجزي

توقيع المريض		التاريخ	اليوم	الشهر	السنة

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

November,2025

Ver. no. 0001

OMDEGZI (Lenalidomide)

Dispense Authorisation Form (DAF)

Name of treating hospital	
Patient date of birth	Patient Initials (first, middle, last)
Prescribing physician (print)	
Diagnosis	
Is this patient being treated in accordance with NICE guidance for Omdegzi? Y or N	
scheme? Y or N	

Capsule strength prescribed	5mg		10mg		15mg		25mg	

Please enter the cycle number of Omdegzi prescribed for this patient	

Please tick all boxes that apply

Woman of non-childbearing potential	

Male	

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Ver. no. 0001

The patient has been councelled about the teratogenic risk of treatment with Omdegzi and understand the need to use a condom if involved in sexual activity with a woman of childbearing potential (even if the patient has had a vasectomy).	

Note to pharmacist – do not dispense unless ticked

Woman of childbearing potential	
The patient has been counselled about the teratogenic risk of treatment and the need to avoid pregnancy, and has been on effective contraception for at least 4 weeks?	

Date of last negative pregnancy test								

Note to pharmacist – do not dispense unless ticked and a negative test has been conducted pharmacy within 3 days prior of the prescription date

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November,2025

Ver. no. 0001

Both signatures must be present prior to dispensing Omdegzi

Dispenser's declaration

I am a physician experienced in managing haematological malignancy and I have read and understood the Omdegzi Healthcare Professional's Information Pack and confirm that the patient has signed an informed consent for Omdegzi treatment.

Sign	Date								
	Bleep								

Print																

Note to pharmacist – prescription and Prescription Authorisation Form must have the same date

Pharmacist's declaration

I am satisfied that this Omdegzi Prescription Authorisation Form has been completed fully, confirm that dispensing is taking place within 7 days of the date of prescription and that I have read and understood the Omdegzi Healthcare Professional's Information Pack.

Sign	Date								
	Bleep								

Print																

Name and post code of dispensing pharmacy	

Date faxed to Alpha Pharma								

Faxed by (Name)																

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November,2025

Ver. no. 0001

OMDEGZI (Lenalidomide)

Prescription Authorisation Form (PAF)

OMDEGZI (Lenalidomide)

Prescription Authorisation Form (PAF)

Name of treating hospital	
Patient date of birth	Patient Initials (first, middle, last)
Prescribing physician (print)	
Diagnosis	
Is this patient being treated in accordance with NICE guidance for Omdegzi? Y or N	
CE guida ptions scheme? Y or N	

Capsule strength prescribed	5mg		10mg		15mg		25mg	

Please enter the cycle number of Omdegzi prescribed for this patient	

Please tick all boxes that apply

Woman of non-childbearing potential	
Male	
The patient has been councelled about the teratogenic risk of treatment with Omdegzi and understand the need to use a condom if involved in sexual activity with a woman of childbearing potential (even if the patient has had a vasectomy).	

Note to pharmacist – do not dispense unless ticked

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Ver. no. 0001

Woman of childbearing potential								
The patient has been counselled about the teratogenic risk of treatment and the need to avoid pregnancy, and has been on effective contraception for at least 4 weeks?								
Date of last negative pregnancy test	D	D	M	M	Y	Y	Y	Y

Note to pharmacist – do not dispense unless ticked and a negative test has been conducted pharmacy within 3 days prior of the prescription date

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

November,2025

Ver. no. 0001

Both signatures must be present prior to dispensing Omdegzi

Dispenser's declaration (Consultants only)

I am a physician experienced in managing haematological malignancy and I have read and understood the Omdegzi Healthcare Professional's Information Pack and confirm that the patient has signed an informed consent for Omdegzi treatment.

Sign	Date								
	Bleep								

Print																

Note to pharmacist – prescription and Prescription Authorisation Form must have the same date

Pharmacist's declaration

I am satisfied that this Omdegzi Prescription Authorisation Form has been completed fully, confirm that dispensing is taking place within 7 days of the date of prescription and that I have read and understood the Omdegzi Healthcare Professional's Information Pack.

Sign	Date								
	Bleep								

Print																

Name and post code of dispensing pharmacy	

Date faxed to Alpha Pharma									

Faxed by (Name)																

This form based on the brand.

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

November,2025

Ver. no. 0001

Pregnancy reporting form

Please complete this form to report a pregnancy in a patient (or in a female partner of a male patient) treated with Omegzi.

As part of Alpha Pharma Safety Monitoring System, it is essential that we follow-up on all reported pregnancies.

Alpha Pharma will therefore be in contact with you for further information in due course and would value your co- operation to ensure we are able to obtain all relevant information regarding foetal exposure to our products.

Please fax or email immediately to Alpha Pharma Drug Safety at the number/address below:

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 steet,Al-Olaya district, Riyadh, Saudi Arabia.

Email: pv@alphapharma.com.sa

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

Or

The National Pharmacovigilance Centre (NPC)
Call Center: 19999
E-mail: npc.drug@sfda.gov.sa
Online: https://ade.sfda.gov.sa

Reporter's Details

Title: Mr, Mrs, Miss, Ms, Dr. etc	First Name(s):	Surname:
Job Title:		
Address:		
City, town:	County:	
Post code:	Country:	
Phone Number:	Fax Number:	
Email address:		

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November,2025

Ver. no. 0001

Female patient information

Patient ID:	Age:	Date of Birth:	DD	MM	YYYY

Female partner of male patient information

Patient ID:	Age:	Date of Birth:	DD	MM	YYYY

Exposure of a pregnant female – not patient or patient partner

Patient ID:	Age:	Date of Birth:	DD	MM	YYYY

Treatment information: Omegzi.

Batch No.:		Expiry date:		Dose:			Frequency:		
Start Date:	DD	MM	YYYY		Stop date:	DD	MM	YYYY	
Indication for use:									

Menses information Pregnancy

Date of last menses:	DD	MM	YYYY	Regular menses: No?	TICK	Yes?	TICK

Information

Has the pregnancy been confirmed?	No?	TICK	Yes?	TICK
Estimated gestational stage:	Estimated date of delivery:	DD	MM	YYYY
Has the patient already been referred to an obsterician / gynaecologist?	No?	TICK	Yes?	TICK

If yes, please specify his/her name annd contact detail

Name:	Contact:

Reporter

Signature:		Date:	DD	MM	YYYY

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Background Information on Reason For Pregnancy

	Yes	No
Was patient erroneously considered not to be of child bearing potential		
If yes, state reason for considering not to be of childbearing potential		
a. Age< 50 3 years and naturally amenorrhoeic* for <1 3 year *amenorrhoea following cancer therapy or during lactation does not rule out childbearing potential		
b. Premature ovarian failure confirmed by a specialist gynaecologist		
c. Previous bilateral salpingo-oophorectomy, or hysterectomy		
d. XV genotype, Turner syndrome, uterine agenesis.		
Indicate from the list below what contraception was used		
a. Implant		
b. Levonorgestrel-releasing intrauterine system (IUS)		
c. Medroxyprogesterone acetate depot		
d. Tubal sterilization (specify below)		
I. Tubal ligation		
II. Tubal diathermy		
III. Tubal clips		
e. Sexual intercourse with a vasectomised male partner only; vasectomy must be confirmed by two negative semen analyses		
f. Ovulation inhibitory progesterone-onlypills (i.e., desogestrel)		
g. Other progesterone-only pills		
h. Combined oral contraceptive pill		
i. Other intra-uterine devices		
j. Condoms		
k. Cervical cap		

l. Sponge		
m. Withdrawal		
n. Other		
o. None		
Indicate from the list below the reason for contraceptive failure		
Missed oral contraception		
Other medication or intercurrent illness interacting with oral contraception		
Identified mishap with barrier method		
Unknown		
Had the patient committed to complete and continuous abstinence		
Was lenalidomide started despite patient already being pregnant		
Did patient receive educational materials on the potential risk of teratogenicity		
Did patient receive instructions on need to avoid pregnancy		

Prenatal Information

Date of last menstural period:	Estimated delivery Date:

PREGNANCY TEST	REFERENCE RANGE	DATE
Urine Qualitative		
Serum quantitative		

Past Obstretric History

Year of pregnancy	Outcome					
	Spontaneous abortion	Therapeutic abortion	Live birth	Still birth	Gestational Age	Type of delivery

Birth defects

	Yes	No	Unknown
Was there any birth defect from any pregnancy			
Is there any family history of any congenital abnormality abstinence			
If yes to either of these questions, please provide details below:			

Maternal Past Medical History

Condition	Dates	Treatment	Outcome	
	From	To		

Maternal Current Medical Conditions

Condition	From	Treatment

Maternal Social History

	Yes	No
Alcohol		
If yes, amount/units per day:		
Tobacco		
If yes, amount per day:		
IV or recreational drug use		
If yes, provide details		

MATERNAL MEDICATION DURING PREGNANCY AND IN 4 WEEKS BEFORE PREGNANCY
(including herbal, alternative and over the counter medicines and dietary supplements)

Medication/treatment	Start Date	Stop date / Continuing	Indication

Name of person completing this form	Signature	Date

*This form based on the brand

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