Amarox

PREGNANCY PREVENTION PROGRAM

Lenamid *(lenalidomide)*

October, 2024
Ver. no. 02

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

Introduction

LENALIDOMIDE (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)

LENALIDOMIDE is a thalidomide analogue, a known human teratogenic substance that causes severe life-threatening birth defects. If LENALIDOMIDE is taken during pregnancy a teratogenic effect cannot be ruled out. LENALIDOMIDE 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 LENALIDOMIDE for ANY patient.

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

The pack also includes:

- Prescription authorisation forms (which must be completed for each prescription of LENALIDOMIDE – see later)
- A pharmacy authorisation agreement (all pharmacies dispensing LENALIDOMIDE 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
- A patient information brochure and example informed consent form
- A pregnancy reporting form to assist urgent communication of information to the SAUDI AMAROX Company and the regulatory agencies of any instances of foetal exposure to LENALIDOMIDE
- An example letter containing important risk minimisation information to communicate to the GPs of patients taking LENALIDOMIDE

- 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 SAUDI AMAROX (contact details in Section 5) or by speaking to any SAUDI AMAROX representative.

The Pregnancy Prevention Programme (PPP)

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

- Patient and healthcare professional education
- Therapeutic management advice to avoid foetal exposure
- A distribution control system
- Follow-up assessment of the effectiveness of the Programme

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.

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 includes the use of a patient card and/or equivalent tool for prescribing and/or dispensing controls, and the collecting of detailed data relating to the indication in order to monitor closely the off-label use within the national territory. 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 ≥ U1 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
- XY genotype, Turner syndrome, uterine agenesis

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

In view of the potential teratogenic risk of LENALIDOMIDE foetal exposure must be avoided.

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

- Use two effective method of contraception for 4 weeks before therapy, during therapy, and until two reliable methods after LENALIDOMIDE therapy, and even in case of dose interruption
- You must not take LENALIDOMIDE if you are pregnant, as it is expected to be harmful to an unborn baby.
- You must not become pregnant while taking LENALIDOMIDE . There
- fore you must use effective methods of contraception if you are a woman of childbearing potential
- If you do become pregnant during your treatment with LENALIDOMIDE , you must stop the treatment and inform your doctor immediately.

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)
- Your patient should be advised that if a pregnancy does occur whilst she is receiving LENALIDOMIDE , she must stop treatment and inform her physician immediately.

Men

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

- Male patients should use condoms throughout the duration of treatment, during dose interruption and for one week 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 must not donate semen during therapy or for one week following the discontinuation of LENALIDOMIDE •

Male patients should be instructed that if their partner becomes pregnant whilst taking LENALIDOMIDE or shortly after he has stopped he should inform his treating doctor immediately.

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 LENALIDOMIDE will only be allowed from pharmacies registered with SAUDI AMAROX. The Company will not authorise supply of LENALIDOMIDE 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

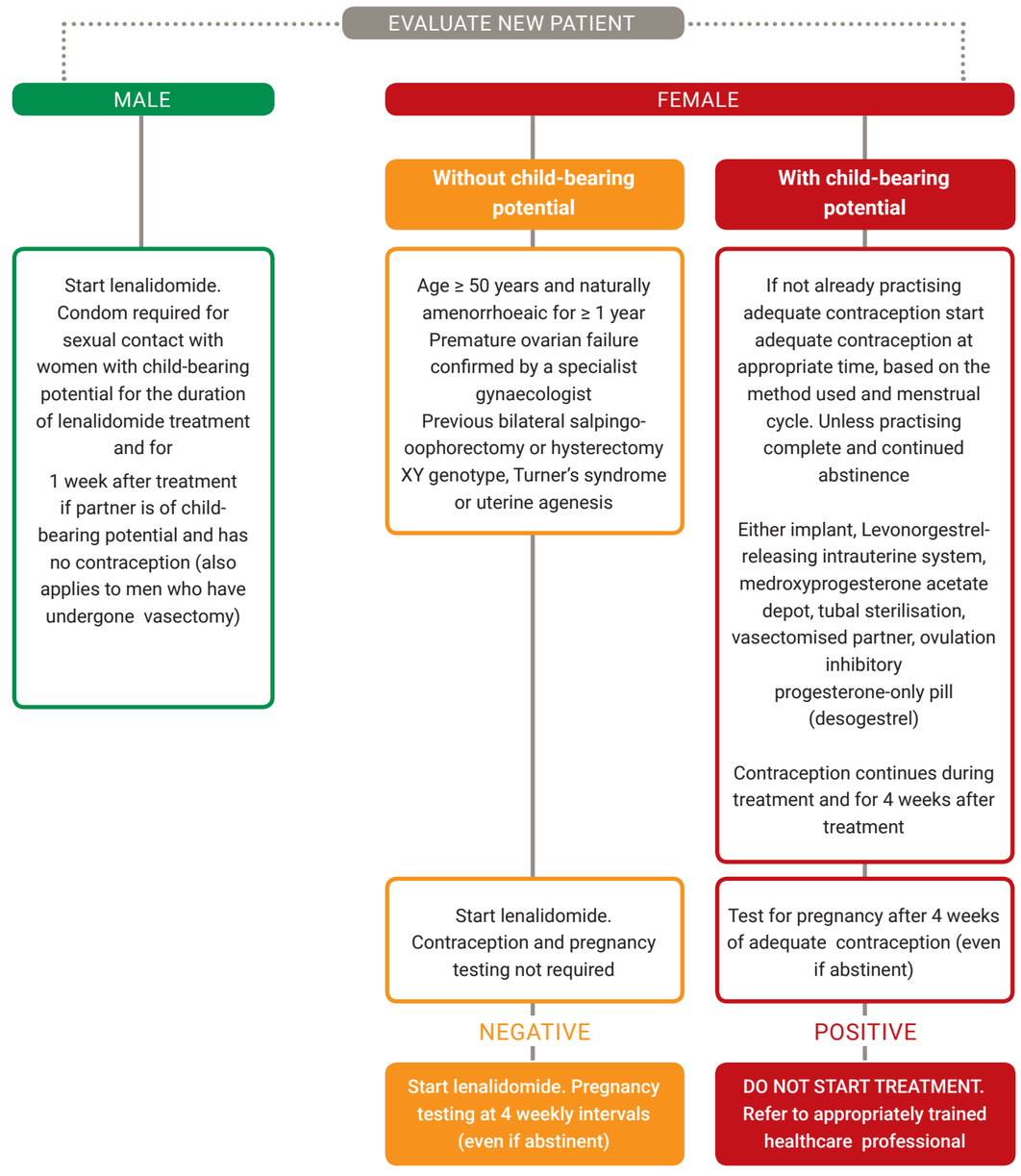
In the event of pregnancy whilst on treatment with LENALIDOMIDE

- Stop treatment
- Refer patient to a physician specialised or experienced in teratology for evaluation and advice Notify SAUDI AMAROX immediately

by contacting the SAUDI AMAROX (contact details in section 5) and completing the Pregnancy Capture Form included in this pack. SAUDI AMAROX will wish to follow-up with you the progress of all pregnancies

- Report the event to the SFDA using the following contact:
  - National Pharmacovigilance and Drug Safety Center
  - Call Center: 19999
  - E-mail: npc.drug@sfda.gov.sa
  - Online: https://ade.sfda.gov.sa
  -

Algorithm For Implementation Of PPP



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 ≥ 2 years *
- Premature ovarian failure confirmed by a gynaecologist
- Female that has not begun menstruation
- Previous bilateral salpingo-oophorectomy, or hysterectomy
- XY genotype, Turner's syndrome, uterine agenesis

**** Amenorrhoea following cancer therapy does not rule out childbearing potential***

Reporting Of Adverse Reactions

The safe use of LENALIDOMIDE is of paramount importance. As part of the ongoing safety monitoring SAUDI AMAROX wishes to learn of Adverse Reactions that have occurred during the use of LENALIDOMIDE .

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

National Pharmacovigilance and Drug Safety Center:

E-mail: **npc.drug@sfda.gov.sa**
Online: **https://ade.sfda.gov.sa**
CALL CENTER **19999**

SAUDI AMAROX And Medical Information Contact Details

Tell: **+966 114 222 413**
MOBILE: **+966 53 121 5235**
Email: **PVSAUDI@AMAROXPHARMA.COM**

Abi Bakr Al Saddiq Branch, Al Yasmeen District, Riyadh 13326, Saudi Arabia

Or

E-mail: **npc.drug@sfda.gov.sa**
Online: **https://ade.sfda.gov.sa**
CALL CENTER **19999**

LENALIDOMIDE Risk Evaluation And Mitigation Strategy (REMS)

Program Education And Prescribing Safety

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 LENALIDOMIDE if pregnant or breastfeeding	
Using at the same time at least 1 highly effective method—tubal ligation, IUD, hormonal (birth control pills, hormonal patches, injections, vaginal rings, or implants), or partner's vasectomy—and at least 1 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 LENALIDOMIDE , while taking LENALIDOMIDE , during dose interruptions, and for at least 4 weeks after stopping LENALIDOMIDE 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 LENALIDOMIDE 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 LENALIDOMIDE	
Not sharing LENALIDOMIDE capsules with anyone—especially with females who can get pregnant	
Not donating blood while taking LENALIDOMIDE (including dose interruptions) and for 4 weeks after stopping LENALIDOMIDE	
Not breaking, chewing, or opening LENALIDOMIDE capsules	
Instructions on LENALIDOMIDE 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 LENALIDOMIDE	
Not sharing LENALIDOMIDE capsules with anyone—especially with females who can get pregnant	
Not donating blood while taking LENALIDOMIDE (including dose interruptions) and for 4 weeks after stopping LENALIDOMIDE	
Not breaking, chewing, or opening LENALIDOMIDE capsules	
Instructions on LENALIDOMIDE 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	

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 LENALIDOMIDE (lenalidomide) 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 LENALIDOMIDE	
Not sharing LENALIDOMIDE capsules with anyone—especially with females who can get pregnant	
Not donating blood or sperm while taking LENALIDOMIDE (including dose interruptions) and for 4 weeks after stopping LENALIDOMIDE	
Not breaking, chewing, or opening LENALIDOMIDE capsules	
Instructions on LENALIDOMIDE dose and administration	
Milligram (mg) Strength:	**Number of Capsules Dispensed:**

MALE CHILDREN (<18 YEARS OF AGE)

Parent or legal guardian must have read the LENALIDOMIDE 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: +966 114 222 413

Abi Bakr Al Saddiq Branch, Al Yasmeen District,
Riyadh 13326, Saudi Arabia

National Pharmacovigilance and Drug Safety Center:

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

Online: **https://ade.sfda.gov.sa**

CALL CENTER 19999

Please see full Prescribing Information, including Boxed Warnings, Contraindications, Warnings And Precautions, and Adverse Reactions, enclosed

Treatment Initiation Form

Treatment Initiation Form

Warning: Severe life-threatening birth defects. If LENALIDOMIDE 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

LENALIDOMIDE 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 LENALIDOMIDE 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

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 LENALIDOMIDE	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 LENALIDOMIDE	Patient initials
I understand that before starting LENALIDOMIDE 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 LENALIDOMIDE 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 LENALIDOMIDE will be prescribed ONLY for me. I must not share it with ANYONE	Patient initials
I have read the LENALIDOMIDE patient booklet and understand the contents, including the information about other possible health problems (side effects) from LENALIDOMIDE	Patient initials
I know that I cannot donate blood while taking LENALIDOMIDE , or for 1 week after stopping treatment	Patient initials
I understand that I must return any unused LENALIDOMIDE 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 Con irmation

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

Prescriber Signature:		**Date:**	DD	MM	YYYY

This form based on the brand

يرجى قراءة المربع المجاور بالكامل ووضع علامة ✓ إذا كنت توافق

اتفهم أن هناك عيوب خلقية شديدة يمكن أن تحدث للجنين عند استخدام اللينياليدوميد 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 لينياليدوميد	
أتفهم أنني يجب أن لا أتناول اللينياليدوميد إذا كنت حامل أو أخطط للحمل.	
اتفهم أنه لا بد لي من استخدام طريقتين فعالة للوقاية من الحمل دون انقطاع , ٤ أسابيع قبل بدء العلاج، طوال مدة العلاج، و ٤ 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 لينياليدوميد	
اتفهم أنه قبل البدء في استخدام علاج لينياليدوميد يجب أن أجري اختباراً للحمل.	
سوف أجري اختبار الحمل كل ٤ أسابيع أثناء فترة العلاج ، واختبار نهائي بعد ٤ أسابيع من نهاية استخدام العلاج	
اتفهم أنه يجب علي التوقف عن تناول لينياليدوميد فوراً وإبلاغ طبيبي إذا حصل حمل أثناء تناول الدواء , أو إذا تأخر أو عدم إنتظام في فترة الحيض فترة الحيض أو تعرضت لنزيف غير طبيعي , أو الاعتقاد لأي سبب من الأسباب أنني قد اكون حاملا .	
اتفهم أن لينياليدوميد اس بي سي سوف يتم وصفه لي فقط وعليه يجب أن لا أشاركه مع أي شخص اخر.	
لقد قرأت النشرة الداخلية للمريض الخاصة بمستحضر لينياليدوميد وفهمت محتوياتها ، بما في ذلك المعلومات حول المشاكل الصحية المحتملة الأخرى (الآثار الجانبية)	
أعلم أنه لا يمكنني التبرع بالدم أثناء تناول اللينياليدوميد ، كذلك لمدة ٤ أسابيع من بعد التوقف عن استخدام العلاج	
اتفهم انه عند الانتهاء من العلاج يجب عليّ أن أعيد أي كمية من اللينياليدوميد 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 أنهٌ يمكن لطبيبي البدأ بإستخدام اللينياليدوميد لعلاجي ، و أؤكد أني اتفهم و موافق على متطلبات برنامج اللينياليدوميد

توقيع المريض		**التاريخ**	اليوم	الشهر	السنة

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 LENALIDOMIDE ? Y or N	
Is this patient being treated outside of the final NICE guidance for LENALIDOMIDE ` but eligible for the LENALIDOMIDE Options Scheme? - Y or N	
Capsule strength prescribed:	5 mg / 10 mg / 25 mg
Please enter the cycle number of LENALIDOMIDE prescribed for this patient	

Please tick all boxes that apply

Woman of non-childbearing potential	
Male	
The patient has been counselled about the teratogenic risk of treatment with LENALIDOMIDE and understands 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 within 3 days prior of the prescription date

Both signatures must be present prior to dispensing LENALIDOMIDE

Dispenser's declaration

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

Sign	Date
	Bleep
Print	
Name and postcode of dispensing pharmacy	

Date faxed to SPC	Faxed by (Name)

This form based on the brand

Lenalidomide Dispense Authorisation Form (DAF)

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 LENALIDOMIDE ? Y or N

Is this patient being treated outside of the final NICE guidance for LENALIDOMIDE , but eligible for the LENALIDOMIDE Options Scheme? - Y or N

Capsule strength prescribed: 5 mg | 10 mg | 25 mg

Please enter the cycle number of LENALIDOMIDE prescribed for this patient

Please tick all boxes that apply

Woman of non-childbearing potential

Male

The patient has been counselled about the teratogenic risk of treatment with LENALIDOMIDE and understands 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 within 3 days prior of the prescription date

Both signatures must be present prior to dispensing LENALIDOMIDE

Prescriber's declaration (Consultants only)

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

Sign | Date

Bleep

Print

Name and postcode of dispensing pharmacy

Date faxed to SPC | Faxed by (Name)

This form based on the brand

LENALIDOMIDE
Prescription Authorisation Form (PAF)

Pregnancy Reporting Form

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 LENALIDOMIDE

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

SAUDI AMAROX 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 SAUDI AMAROX at the number/address below:

Tell: **+966 114 222 413**

MOBILE **+966 53 121 5235**

Abi Bakr Al Saddiq Branch, Al Yasmeen District, Riyadh 13326, Saudi Arabia

Email: **PVSAUDI@AMAROXPHARMA.COM**

Or

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

Online: **https://ade.sfda.gov.sa**

CALL CENTER 19999

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:		

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 partner Patient

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

Treatment information: LENALIDOMIDE

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 obstetrician/gynaecologist?	**No?**	TICK	**Yes?**	TICK

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

Name:	**Contact:**

Reporter

Signature:		**Date:**	DD	MM	YYYY

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.	XY 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-only pills (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 menstrual period:	Estimated Delivery Date:

PREGNANCY TEST	REFERENCE RANGE	DATE
Urine Qualitative		
Serum quantitative		

Past Obstretic 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*