Lenalidomide

Pregnancy Prevention Programme

INFORMATION FOR HEALTHCARE PROFESSIONALS PRESCRIBING OR DISPENSING LENALIDOMIDE

Introduction and Overview

Please always refer to the summary of product Characteristics (SmPC), which can be provided to any healthcare professional upon request.

Lenalidomide Pregnancy prevention: If lenalidomide is taken during pregnancy it is expected to cause severe birth defect or death to an unborn baby.

This Programme is designed to make sure that unborn babies are not exposed to lenalidomide. It will provide you with information about how to follow the programme and explain your responsibilities.

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What is Lenalidomide?

Lenalidomide Classification and Indications

Lenalidomide is an immunomodulating medicinal product licensed for treatment of:

Multiple Myeloma: Lenalidomide monotherapy is indicated in the maintenance treatment of adult patients with newly diagnosed multiple myeloma who have undergone autologous stem cell transplantation.

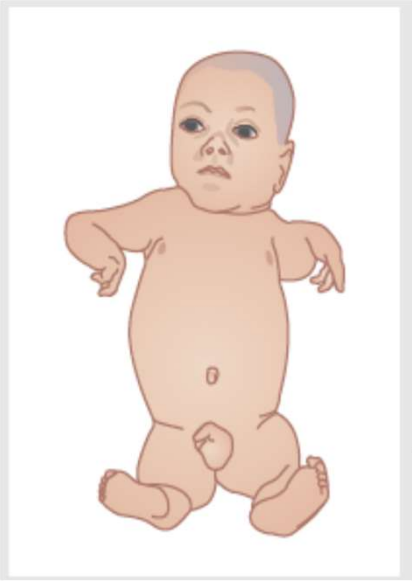
Lenalidomide in combination therapy with dexamethasone, or bortezomib and dexamethasone, or melphalan and prednisone is indicated for the treatment of adult patients with previously treated multiple myeloma who are not candidates for a transplant.

Lenalidomide in combination with dexamethasone is indicated for the treatment of adult patients with multiple myeloma who have received at least one prior treatment.

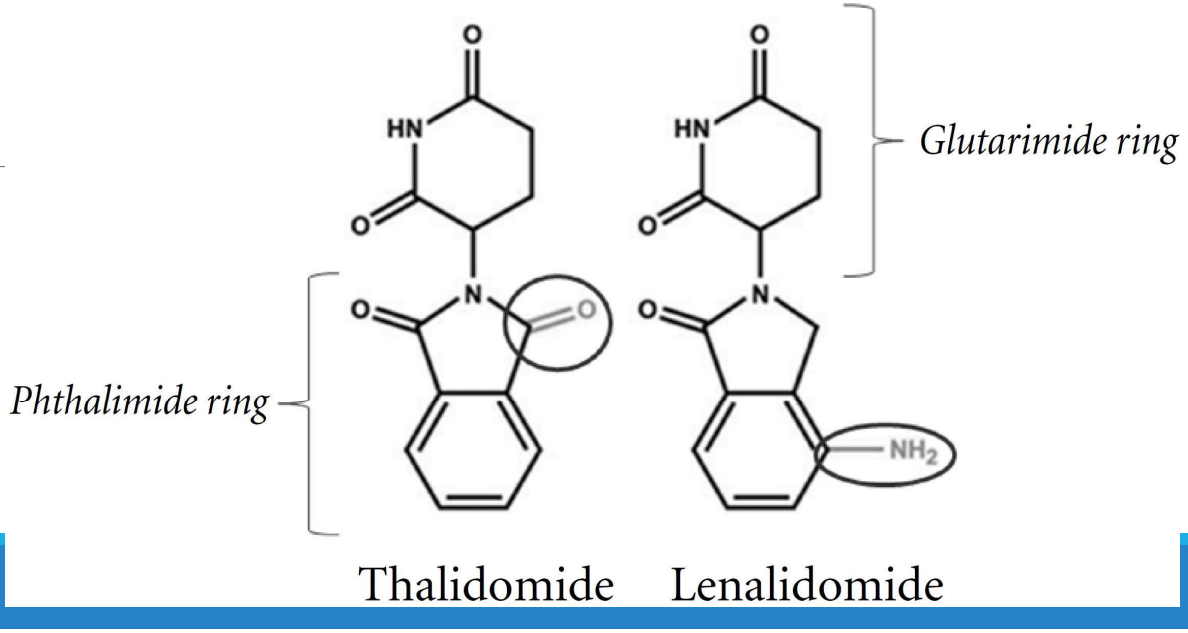
Follicular Lymphoma: Lenalidomide in combination with rituximab (anti-CD20 antibody) is indicated for the treatment of adult patients who have received prior treatment for follicular lymphoma (Grade 1-3a).

Lenalidomide Pregnancy Prevention Programme

Lenalidomide is structurally related to thalidomide



If lenalidomide is taken during pregnancy, a teratogenic effect is expected. Therefore, lenalidomide is contraindicated in pregnancy and in women of childbearing potential unless the conditions of the Pregnancy Prevention Programme are met.



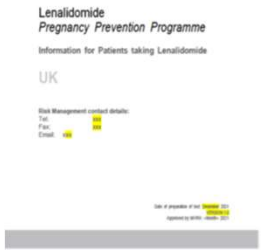
Pregnancy Prevention Measures

- It is a requirement of the Pregnancy Prevention Programme that all Healthcare Professionals ensure they have read and understood this information before prescribing or dispensing lenalidomide for any patient

- All men and all women of childbearing potential should undergo, at treatment initiation, counselling of the need to avoid pregnancy. Patients should comply with requirements of safe use of lenalidomide

Pregnancy Prevention Measures

- Patients must be provided with the appropriate Patient Brochure


Lenalidomide
Pregnancy Prevention Programme
Information for Patients taking Lenalidomide
UK

- Treatment Initiation Form

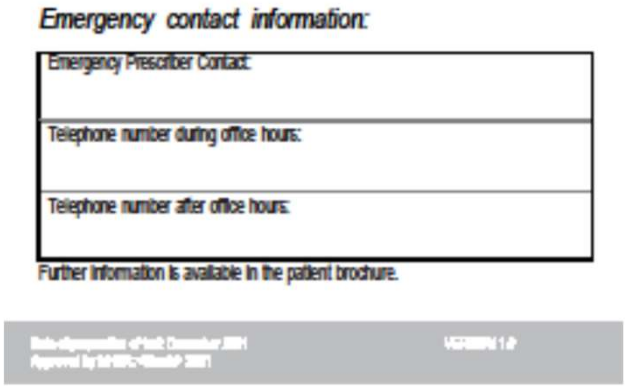
Male Patients

Female (non Child Bearing) patients

Female (Child Bearing) patients

Pregnancy Prevention Measures

- Patient Pocket Information Card. – Already provided for each pack supplied by EJB



Emergency contact information:

Emergency Prescriber Contact:
Telephone number during office hours:
Telephone number after office hours:

Further information is available in the patient brochure.

- **You must ensure that your patient fully understands what you have told them about lenalidomide before starting the treatment.**

Lenalidomide Prescription Authorisation Form (PAF)

A newly completed copy of this form MUST accompany EVERY lenalidomide prescription. Completion of this information is mandatory for ALL patients.

Name of treating Hospital							
Patient Date of Birth	D D M M Y Y Y Y	Patient ID Number/Initials					
Prescribing physician: (print)							
Indication: (tick)	Multiple Myeloma ☐						
Line of therapy (please specify):	1st ☐	2nd ☐	3rd ☐	4th+ ☒			
Myelodysplastic Syndromes with isolated del5q cytogenetic abnormality:							
Low- ☐	or intermediate-1 risk ☐						
Mantle Cell Lymphoma relapsed and/or refractory ☐	Follicular Lymphoma ☐						
Other ☐ If other please specify:							

Capsule strength prescribed: (tick)	2.5mg ☐	5mg ☐	7.5mg ☐	10mg ☐	15mg ☐	20mg ☐	25mg ☐
Quantity of **Capsules per cycle** prescribed:*							
Number of cycle(s) prescribed	1 ☐	2 ☐	3 ☐	Other ☐ specify number of cycles:			
Total number of Capsules				* Do NOT enter number of Packs			

Woman of non-childbearing potential	TICK	
Male	TICK	
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 not using effective contraception or if their partner is pregnant (even if the patient has had a vasectomy).	Y	N

Note to pharmacist – do not dispense unless ticked yes

Woman of childbearing potential (maximum 4 weeks prescription only)	TICK	
The patient has been counselled about the teratogenic risk of treatment, the need to avoid pregnancy, and has been on effective contraception for at least 4 weeks or committed to absolute and continuous abstinence confirmed on a monthly basis.	Y	N
Date of last negative pregnancy test	D D M M Y Y Y Y	

Note to pharmacist – do not dispense unless ticked yes and a negative test has been conducted within 3 days prior of the prescription date, and dispensing is taking place within 7 days of the prescription date.

Both signatures must be present prior to dispensing lenalidomide

Prescriber's declaration

As the Prescriber, I fully understand the implications of prescribing Lenalidomide. I confirm the information provided on this PAF is accurate, complete and in accordance with the pregnancy prevention measures for lenalidomide. I confirm treatment has been initiated and is monitored under the supervision of a physician experienced in managing immunomodulatory drugs.

Sign	Date	D D M M Y Y Y Y
	Bleep	
Print		

Pharmacist Confirmation

Information which was not completed by the Prescriber and is needed to confirm the required pregnancy prevention measures has been obtained by the Pharmacist (e.g. confirmation from the Prescriber and/or patient) and documented in this form.

To indicate any changes/corrections made in the PAF, please add your initials and date against the changes. Yes ☐ Not Applicable ☐

Pharmacist declaration

I am satisfied that this Lenalidomide Prescription Authorisation Form has been completed fully and that I understand the implications of dispensing Lenalidomide to a patient.

I am dispensing no more than 4 weeks supply to women of childbearing potential and 12 weeks for males and women of non-childbearing potential.

Sign	Date	D D M M Y Y Y Y
	Bleep	
Print		
Name and postcode of dispensing pharmacy		

Home delivery information

Name and postcode of Home delivery company used, if applicable.	

A copy of every completed PAF should be sent to E.J. Busuttil Limited immediately after dispensing (email: info@ejbusuttil.com)

Date sent to E.J. Busuttil Limited D D M M Y Y Y Y Sent by (Name)

Date of preparation of text: February 2022

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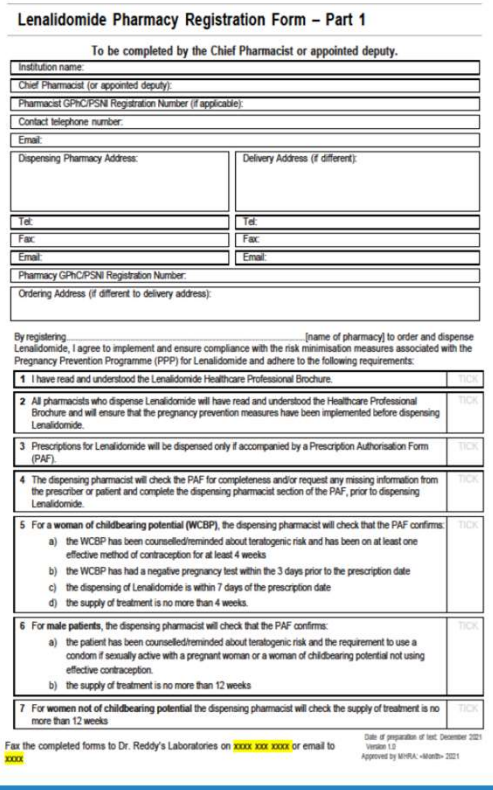
Prescriber & Dispenser Duties

- Pharmacy Registration Form



Lenalidomide Pharmacy Registration Form – Part 1

To be completed by the Chief Pharmacist or appointed deputy.

Institution name:	
Chief Pharmacist (or appointed deputy):	
Pharmacist GPhC/PSNI Registration Number (if applicable):	
Contact telephone number:	
Email:	
Dispensing Pharmacy Address:	Delivery Address (if different):
Tel:	Tel:
Fax:	Fax:
Email:	Email:
Pharmacy GPhC/PSNI Registration Number:	
Ordering Address (if different to delivery address):	

By registering ..... [name of pharmacy] to order and dispense Lenalidomide, I agree to implement and ensure compliance with the risk minimisation measures associated with the Pregnancy Prevention Programme (PPP) for Lenalidomide and adhere to the following requirements:

1 I have read and understood the Lenalidomide Healthcare Professional Brochure.	TICK
2 All pharmacists who dispense Lenalidomide will have read and understood the Healthcare Professional Brochure and will ensure that the pregnancy prevention measures have been implemented before dispensing Lenalidomide.	TICK
3 Prescriptions for Lenalidomide will be dispensed only if accompanied by a Prescription Authorisation Form (PAF).	TICK
4 The dispensing pharmacist will check the PAF for completeness and/or request any missing information from the prescriber or patient and complete the dispensing pharmacist section of the PAF, prior to dispensing Lenalidomide.	TICK
5 For a **woman of childbearing potential (WCBP)**, the dispensing pharmacist will check that the PAF confirms: a) the WCBP has been counselled/reminded about teratogenic risk and has been on at least one effective method of contraception for at least 4 weeks b) the WCBP has had a negative pregnancy test within the 3 days prior to the prescription date c) the dispensing of Lenalidomide is within 7 days of the prescription date d) the supply of treatment is no more than 4 weeks.	TICK
6 For **male patients**, the dispensing pharmacist will check that the PAF confirms: a) the patient has been counselled/reminded about teratogenic risk and the requirement to use a condom if sexually active with a pregnant woman or a woman of childbearing potential not using effective contraception. b) the supply of treatment is no more than 12 weeks	TICK
7 For **women not of childbearing potential** the dispensing pharmacist will check the supply of treatment is no more than 12 weeks	TICK

Fax the completed forms to Dr. Reddy's Laboratories on xxxx xxx xxxx or email to xxxx

Date of preparation of text: December 2021
Version 1.0
Approved by MHRA: <Month> 2021

Prescriber & Dispenser Duties

- All patients should be given a Patient Brochure and a Patient Information Card to take home – these materials remind patients of the key educational information and risks of treatment, and have been already provided to CPSU/MDH for every pack of Lenalidomide Dr Reddys 5mg Hard Capsules supplied.

- **Patients should be advised not to donate blood during treatment and for at least 7 days after cessation of treatment with lenalidomide.**

Women of Childbearing Potential

Women of Childbearing Potential

Women in the following groups are considered not to have childbearing 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 or during breastfeeding does not rule out childbearing potential
- Premature ovarian failure confirmed by a specialist gynaecologist
- Previous bilateral salpingo-oophorectomy, or hysterectomy
- XY genotype, Turner syndrome, uterine agenesis.

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

For women of childbearing potential, prescriptions of lenalidomide should be limited to a maximum duration of 4 weeks according to the approved indications dosing regimens and continuation of treatment requires a new prescription. Ideally, pregnancy testing, issuing a prescription and dispensing should occur on the same day.

Dispensing of lenalidomide should occur within a maximum of 7 days of the prescription, and the date of the last negative pregnancy test, must be within the 3 days prior to the date of the prescription.

Women of childbearing potential must never take lenalidomide if they are:

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

Women of Childbearing Potential

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

Women of childbearing potential (even if they have amenorrhoea) must:

- use at least one effective method of contraception for at least 4 weeks before therapy, during therapy, and until at least 4 weeks after lenalidomide therapy, and even in case of dose interruption or

- commit to absolute and continuous abstinence, confirmed on a monthly basis.

AND

- have a medically supervised negative pregnancy test (with a minimum sensitivity of 25 mIU/mL) once she has been established on contraception for at least 4 weeks, at least every 4 weeks during therapy (this includes dose interruptions) and at least 4 weeks after the end of therapy (unless confirmed tubal sterilisation).

Women of Childbearing Potential

There must be no more than 3 days between the dates of the last negative pregnancy test and the prescription. Best practice is for the pregnancy test, prescribing and dispensing to take place on the same day.

If not established on effective contraception, patient must be referred to a trained healthcare professional for contraceptive advice in order that contraception can be initiated, such as:

- 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).

TREATMENT FOR A WOMAN OF CHILDBEARING POTENTIAL CANNOT START UNTIL 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.

Core Requirements of the Pregnancy Prevention Programme

- All healthcare professionals dispensing or prescribing lenalidomide must read the Lenalidomide Healthcare Professional's Information Pack
- All pharmacies who dispense lenalidomide must agree to implement risk minimisation according to this Pregnancy Prevention Programme
- Every prescription for lenalidomide must be accompanied by a Prescription Authorisation Form, which must be completed by the prescriber and the pharmacist and a copy sent to E.J. Busuttil Limited.
- Your patient should be advised that if a pregnancy does occur whilst she is receiving lenalidomide, she must stop treatment immediately and inform her prescriber.

You must send a copy of every completed Prescription Authorisation Form immediately to E.J. Busuttil Limited, for ALL patients, regardless of indication. This is an absolute requirement so that we can fulfil regulatory obligations to monitor adherence and off-label usage.

Other Considerations

KEEPING IN MIND ADDITIONAL SIDE EFFECTS OF LENALIDOMIDE

Venous Thromboembolism (VTE)

Because of the increased risk of VTE in patients with multiple myeloma taking lenalidomide, and to a lesser extent in patients with multiple myeloma, myelodysplastic syndromes and mantle cell lymphoma taking lenalidomide monotherapy, combined oral contraceptive pills are not recommended.

The risk of venous thromboembolism continues for 4 to 6 weeks after discontinuing combined oral contraception. The efficacy of contraceptive steroids may be reduced during co-treatment with dexamethasone.

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

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

Other Considerations

MALE PATIENTS, OR PARTNERS OF FEMALE PATIENTS

Lenalidomide is Teratogenic

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

Lenalidomide is present in semen. Therefore, all male patients should use condoms throughout treatment duration, during dose interruption and for at least 7 days after cessation of treatment if their partner is pregnant or of childbearing potential who is not using effective contraception and even if the male patient has undergone vasectomy.

Patients should be instructed that if their partner does become pregnant whilst he is taking lenalidomide or within 7 days after he has stopped taking lenalidomide, he should inform his prescriber immediately. The partner should inform her physician immediately. It is recommended that she be referred to a physician specialised in teratology for evaluation and advice.

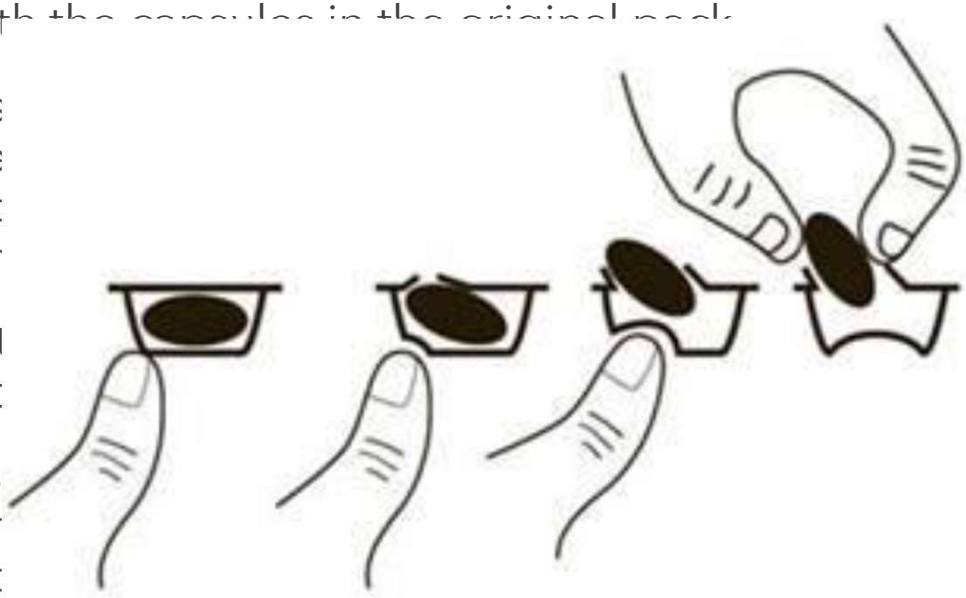
Male patients should not donate semen or sperm during treatment, including during dose interruptions and for at least 7 days following discontinuation of lenalidomide.

Handling Lenalidomide

FOR HEALTHCARE PROFESSIONALS AND CAREGIVERS

Handling Lenalidomide

Keep the blisters wit

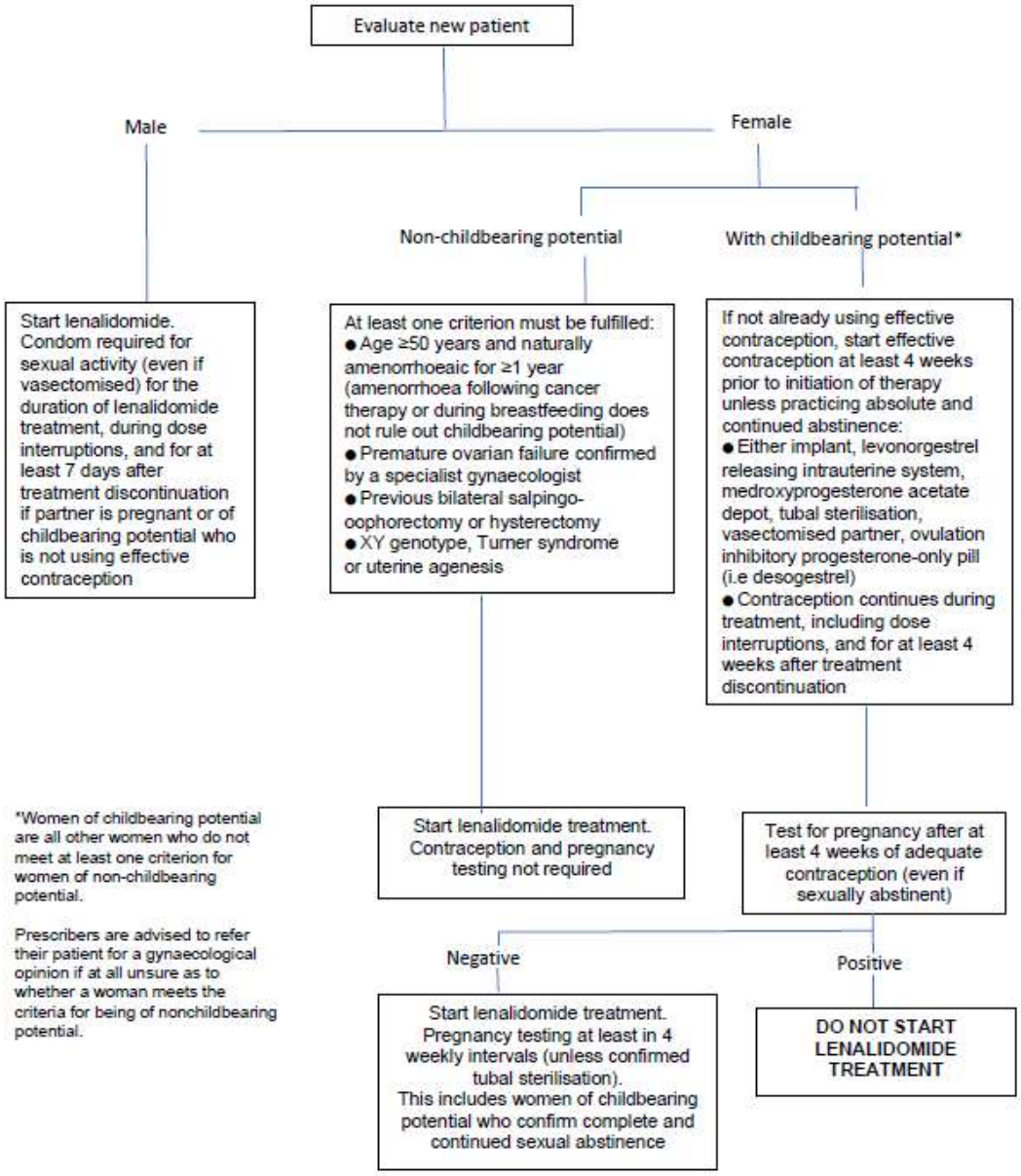


Capsules can occas m out of the blister, especially when the ule. Capsules should not be pressed out ddle nor by putting pressure on both er ing of the capsule.

It is recommended t efore the pressure is located to one site c tion or breakage.

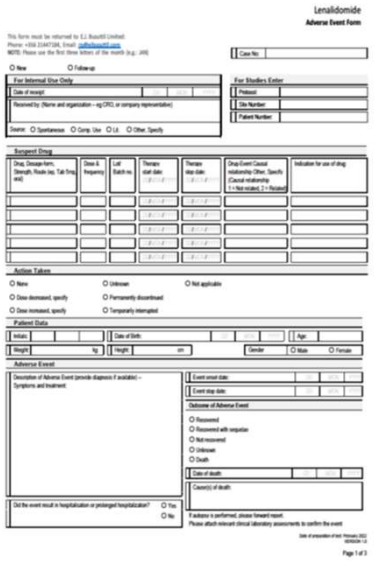
Healthcare profess sable gloves when handling the blister carefully to prevent skin exposure, plac and disposed of in accordance with local requirements. Hands should then be washed thoroughly with soap and water. Women who are pregnant or suspect they may be pregnant should not handle the blister or capsule.

Handling Lenalidomide


Evaluate new patient
Male
Female
Non-childbearing potential
With childbearing potential*
Start lenalidomide. Condom required for sexual activity (even if vasectomised) for the duration of lenalidomide treatment, during dose interruptions, and for at least 7 days after treatment discontinuation if partner is pregnant or of childbearing potential who is not using effective contraception
At least one criterion must be fulfilled:
● Age ≥50 years and naturally amenorrhoeaic for ≥1 year (amenorrhoea following cancer therapy or during breastfeeding does not rule out childbearing potential)
● Premature ovarian failure confirmed by a specialist gynaecologist
● Previous bilateral salpingo-oophorectomy or hysterectomy
● XY genotype, Turner syndrome or uterine agenesis
If not already using effective contraception, start effective contraception at least 4 weeks prior to initiation of therapy unless practicing absolute and continued abstinence:
● Either implant, levonorgestrel releasing intrauterine system, medroxyprogesterone acetate depot, tubal sterilisation, vasectomised partner, ovulation inhibitory progesterone-only pill (i.e desogestrel)
● Contraception continues during treatment, including dose interruptions, and for at least 4 weeks after treatment discontinuation
*Women of childbearing potential are all other women who do not meet at least one criterion for women of non-childbearing potential.
Prescribers 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 nonchildbearing potential.
Start lenalidomide treatment. Contraception and pregnancy testing not required
Test for pregnancy after at least 4 weeks of adequate contraception (even if sexually abstinent)
Negative
Positive
Start lenalidomide treatment. Pregnancy testing at least in 4 weekly intervals (unless confirmed tubal sterilisation). This includes women of childbearing potential who confirm complete and continued sexual abstinence
DO NOT START LENALIDOMIDE TREATMENT

FOR COMPLETE INFORMATION ON POSOLOGY, DOSAGE AND METHOD OF ADMINISTRATION ENSURE TO REFER

TO THE AUTHORISED SUMMARY OF PRODUCT CHARACTERISTICS



Lenalidomide

Adverse Event Form

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINE

Lenalidomide Dr. Reddys 2.5 mg hard capsules EFG
Lenalidomide Dr. Reddys 5 mg hard capsules EFG
Lenalidomide Dr. Reddys 7.5 mg hard capsules EFG
Lenalidomide Dr. Reddys 10 mg hard capsules EFG
Lenalidomide Dr. Reddys 15 mg hard capsules EFG
Lenalidomide Dr. Reddys 20 mg hard capsules EFG
Lenalidomide Dr. Reddys 25 mg hard capsules EFG

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each capsule contains 2.5 mg lenalidomide
Each capsule contains 5 mg lenalidomide
Each capsule contains 7.5 mg lenalidomide
Each capsule contains 10 mg lenalidomide
Each capsule contains 15 mg lenalidomide
Each capsule contains 20 mg lenalidomide
Each capsule contains 25 mg lenalidomide

Excipients with known effect:

Each capsule contains 33.2 mg lactose
Each capsule contains 66.4 mg lactose
Each capsule contains 99.7 mg lactose
Each capsule contains 132.9 mg lactose
Each capsule contains 199.3 mg lactose
Each capsule contains 265.8 mg lactose
Each capsule contains 332.2 mg lactose

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Hard capsules

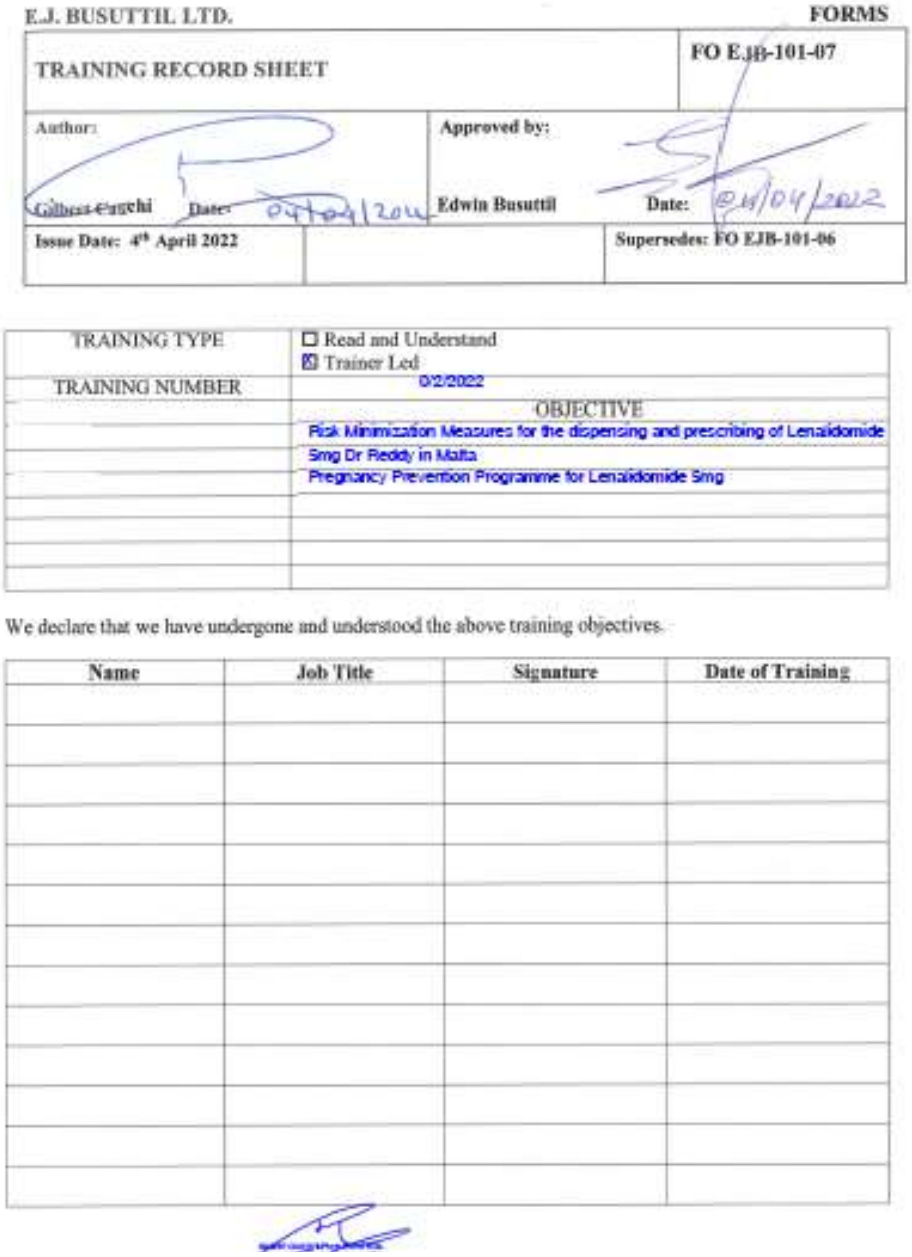
White opaque body and opaque green to light green head, with an approximate length of 14.3 mm, marked with "L9NL" and "2.5".
White opaque body and white opaque head, with an approximate length of 18.0 mm, marked with "L9NL" and "5".
White opaque body and yellow opaque head, with an approximate length of 18.0 mm, marked with "L9NL" and "7.5".
Opaque yellow body and opaque green to light green head , with an approximate length of 21.7 mm, marked with "L9NL" and "10".
White opaque body and opaque head blue to light blue, with an approximate length of 21.7 mm, marked with "L9NL" and "15".
Opaque body blue to light blue and opaque head green to light green, with an approximate length of 21.7 mm, marked with "L9NL" and "20".
White opaque body and white opaque head, with an approximate length of 21.7 mm, marked with "L9NL" and "25".

1 of 51

REPORTING OF ANY ADVERSE DRUG EVENTS

TRAINING FORM

KINDLY COMPLETE AND SEND AS A SCAN THE RELEVANT TRAINING FORMS



E.J. BUSUTTIL LTD. FORMS

TRAINING RECORD SHEET		FO EJB-101-07
Author: Gilbert Cachia Date: 04/04/2022	Approved by: Edwin Busuttil	Date: 04/04/2022
Issue Date: 4th April 2022		Supersedes: FO EJB-101-06

TRAINING TYPE	☐ Read and Understand ☒ Trainer Led
TRAINING NUMBER	02/2022
	OBJECTIVE
	Risk Minimization Measures for the dispensing and prescribing of Lenalidomide
	Smg Dr Reddy in Malta
	Pregnancy Prevention Programme for Lenalidomide Smg

We declare that we have undergone and understood the above training objectives.

Name	Job Title	Signature	Date of Training

ej.busuttil

Address:
Busuttil Buildings, Triq l-Ghadam
Central Business District Zone 1
Birkirkara CBD1060

Telephone:
+356 21447184

Emails:
info@ejbusuttil.com
rp@ejbusuttil.com

Kindly note that while all the information provided in this presentation is relevant to any dose of Lenalidomide, for any patient – E.J. Busuttil Limited has only provided a select number of packs of **Lenalidomide Dr Reddys 5mg Hard Capsules**.

Information relating to patients initiated on other brands or doses should be sent to the local distributor accordingly.

All forms, brochures and other information are accessible in this SharePoint:

https://ejbusuttil-my.sharepoint.com/:f:/p/gilbert/EldhbhnjLG1JgYW7bh-ryYUBCM4KEXpC4QV_zDbJOpNW4A?e=Y6PuR1