Lenalidomide (OMDEGZI) Pregnancy Prevention Programme

Male Risk Awareness Form

Risk Awareness Form for counselling the patient to ensure the patient is fully informed about the safe use of lenalidomide

This Risk Awareness Form is to assist you with counselling a patient before they commence lenalidomide treatment in order to ensure the medicine is used safely and correctly. A form must be completed for each male patient prior to the initiation of their lenalidomide treatment. This form must be completed by a physician with expertise in managing immunomodulatory drugs.

The purpose of the Risk Awareness Form is to protect patients and any possible foetuses by ensuring that patients are fully informed of and understand the risk of teratogenicity and other adverse drug reactions associated with the use of lenalidomide. It is mandatory that male patients receive counselling and education to be made aware of the risks of lenalidomide.

This form should be retained with the patient's medical records, and a photocopy provided to them. This form is not a contract and does not absolve anybody from his/her responsibilities regarding the safe use of the product and prevention of foetal exposure to lenalidomide.

Warning: Lenalidomide is structurally related to thalidomide. Thalidomide is a known human teratogenic active substance that causes severe life-threatening birth defects. Lenalidomide induced in monkeys malformations similar to those described with thalidomide. If lenalidomide is taken during pregnancy, a teratogenic effect of lenalidomide in humans is expected. The conditions of the Pregnancy Prevention Programme must be fulfilled for all patients unless there is reliable evidence that the patient does not have childbearing potential.

If lenalidomide is taken during pregnancy it is expected to cause severe birth defects or death to an unborn baby.

Patient Details Patient's

First Name:

Patient's Last Name:

Date of Birth:	DD	MM	YYYY
Counselling Date:	DD	MM	YYYY

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

	Male
Did you inform your patient:	
1) Of the need to avoid foetal exposure?	Tick
2) To not share the medicinal product with any other person?	Tick
3) That they should not donate blood during treatment (including during dose interruptions) and for at least 7 days following discontinuation of lenalidomide?	Tick
4) That they should return the unused capsules to the pharmacist at the end of treatment ?	Tick
5) That lenalidomide is found in semen, so there is a need to use condoms if the sexual partner is pregnant or is a woman of childbearing potential not on effective contraception (even if the man has had a vasectomy)?	Tick
6) That if his partner becomes pregnant, he should inform his treating doctor immediately and always use a condom?	Tick

Can you confirm your patient:

Is capable of complying with contraceptive measures?	*YES*	*NO*

Pregnancy Prevention

The Patient Confirms that:

They will use a condom during intercourse with a woman of childbearing potential.	Tick
Their female partner is using an effective method of pregnancy prevention.	Tick
Their female partner is of non-childbearing potential.	Tick
They are committed to complete and absolute abstinence.	Tick

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.

I will comply with all my obligations and responsibilities as the prescriber of lenalidomide.

Prescriber's First Name:

Prescriber's Last Name:

Prescriber's Signature:		Date:	DD	MM	YYYY

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

I understand that severe birth defects are expected to occur with the use of lenalidomide. I have been warned by my prescriber 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 lenalidomide passes into human semen. If my partner is pregnant or able to become pregnant, and she doesn't use effective contraception, I must use condoms throughout the duration of my treatment, during dose interruptions and for at least 7 days after I stop lenalidomide even if I have had a vasectomy.	Patient Initials
I know that I must inform my prescriber immediately if I think that my partner may be pregnant while I am taking lenalidomide or within 7 days after I have stopped taking lenalidomide and my partner should be referred to a physician specialised or experienced in teratology for evaluation and advice	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 Information Guide and understand the contents, including the information about other possible important health problems (side effects) associated with the use of lenalidomide.	Patient Initials
I understand that I cannot donate blood while taking lenalidomide (including dose interruptions) or for at least 7 days after stopping treatment.	Patient Initials
I understand that I must return any unused lenalidomide capsules to my pharmacy at the end of my treatment.	Patient Initials
I have been informed about effective contraceptive methods that my female partner can use.	Patient Initials
I have been informed about the thromboembolic risk and possible requirement to take thromboprophylaxis during treatment with lenalidomide.	Patient Initials

المريض: يرجى القراءة بعناية ووضع الأحرف الأولى من اسمك في المربع المجاور إذا كنت توافق على البيان

أعلم أنه من المتوقع حدوث عيوب خلقية خطيرة عند استخدام لينالیدوميد. وقد حذرني الطبيب من أن أي جنين معرض لخطر كبير للإصابة بعيوب خلقية، وقد يموت إذا كانت المرأة حاملاً أو أصبحت حاملاً أثناء تناول لينالیدوميد.	الأحرف الأولى من اسم المريض
أدرك أن لينالیدوميد ينتقل إلى السائل المنوي البشري. إذا كانت شريكتي حاملاً أو قادرة على الحمل، ولم تستخدم وسائل منع حمل فعالة، فيجب عليّ استخدام الواقي الذكري طوال فترة العلاج، وأثناء فترات انقطاع الجرعات، ولمدة ٧ أيام على الأقل بعد إيقاف لينالیدوميد، حتى لو خضعتُ لعملية قطع القناة الدافقة.	الأحرف الأولى من اسم المريض
أعلم أنه يجب عليّ إبلاغ الطبيب المعالج فورًا إذا كنت أعتقد أن شريكتي قد تكون حاملاً أثناء تناولي للينالیدوميد أو في غضون ٧ أيام بعد توقفي عن تناول اللينالیدوميد، ويجب إحالة شريكتي إلى طبيب متخصص أو خبير في علم التشوهات الخلقية للتقييم والنصيحة.	الأحرف الأولى من

اسم المريض	
الأحرف الأولى من اسم المريض	أدرك أن لينياليدوميد سيُوصف لي وحدي، ولا يُفترض بي أن أشاركه مع أي شخص.
الأحرف الأولى من اسم المريض	لقد قرأت دليل معلومات المريض الخاص باللينياليدوميد وأفهم محتوياته، بما في ذلك المعلومات حول المشاكل الصحية المهمة الأخرى المحتملة (الآثار الجانبية) المرتبطة باستخدام اللينياليدوميد.
الأحرف الأولى من اسم المريض	أفهم أنني لا أستطيع التبرع بالدم أثناء تناول لينياليدوميد (بما في ذلك انقطاع الجرعة) أو لمدة ٧ أيام على الأقل بعد التوقف عن العلاج.
الأحرف الأولى من اسم المريض	أفهم أنه يجب عليّ إعادة أي كبسولات لينياليدوميد غير مستخدمة إلى الصيدلية الخاصة بي في نهاية العلاج.
الأحرف الأولى من اسم المريض	لقد تم إعلامي بوسائل منع الحمل الفعالة التي يمكن لشريكتي استخدامها.
الأحرف الأولى من اسم المريض	لقد تم إعلامي بخطر الإصابة بالجلطات الدموية والحاجة المحتملة لتناول العلاج الوقائي للجلطات أثناء العلاج باللينياليدوميد.

Patient Confirmation

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

I understand that in order to receive lenalidomide as part of the medical care and treatment that I am receiving, my personal data will be collected and processed by my treating healthcare institution and the relevant Marketing Authorisation Holder (i.e. the supplier of lenalidomide) and their processors, HealthBeacon plc and Pharmacare Group Ltd. I further understand that my personal data will be processed and retained in accordance with applicable laws and regulations, as described in the relevant party's privacy policy, which can be found on their website.

Patient Signature:		Date:	DD	MM	YYYY

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Statement of the interpreter (where appropriate)

I have interpreted the information above to the patient/parent to the best of my ability and in a way in which I believe she/he/they can understand. She/he/they agree to follow the necessary precautions to prevent an unborn child being exposed to lenalidomide.

Interpreter Signature:		**Name:** (Print)		**Date**	DD	MM	YYYY

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