Lenalidomide Grindeks

Pregnancy Prevention Programme

Woman of childbearing potential

Risk awareness form

This Risk awareness form must be completed for each patient before starting therapy with lenalidomide.

It is mandatory that each patient receive counselling and education to be made aware of the risks of lenalidomide.

The aim of this Risk awareness form is to protect patients and any possible foetuses by ensuring that patients are fully aware of and understand the risk of teratogenicity and other adverse effects associated with the use of lenalidomide.

Lenalidomide therapy cannot start until the women of childbearing potential have been chosen an effective method of contraception or commits to complete and continuous abstinence.

Lenalidomide therapy can be initiated only when patient has used one effective method of contraception for at least 4 weeks before therapy, or commits to complete and continuous abstinence, and obtains a negative pregnancy test.

This Risk awareness form must be kept with patient's medical records and a copy provided to the patient.

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 information

Patient First Name:	
Patient Last Name:	
Date of Birth:	
Patient code[1]/initials:	
Counselling Date:	

You must inform your patient:	***Woman of Childbearing Potential*** **Tick**
Of the high teratogenic potential of lenalidomide and the need to avoid foetal exposure.	☐
That if she is pregnant or plans to be, she must not take lenalidomide	☐
About effective contraceptive methods that can be used.	☐
Of the need to avoid lenalidomide during pregnancy and of the need for effective contraception, without interruption, 4 weeks before starting treatment, throughout the entire duration of treatment, and 4 weeks after the end of treatment, or absolute and continued abstinence.	☐
Of the expected consequences of pregnancy and the need to stop treatment and consult rapidly if there is a suspicion of pregnancy.	☐
Of the need to repeat pregnancy test every 4 weeks, including 4 weeks after the end of treatment unless confirmed tubal sterilization.	☐
That if she needs to change or stop using her method of contraception she should inform: a) the prescriber prescribing her contraception that she is taking lenalidomide. b) the prescriber prescribing lenalidomide that she has stopped or changed her method of contraception.	☐
About the risk of thromboembolism and the possible antithrombotic prophylactic measures during treatment with lenalidomide.	☐
About other serious side effects of lenalidomide (please give *Patient Brochure* to the patient).	☐
Not to donate blood during therapy or for 7 days following discontinuation of lenalidomide.	☐
Not to share the medication with any other person.	☐
To return unused capsules to pharmacist.	☐
That dispensing of lenalidomide should occur within 7 days of the prescription.	☐

[1] Please use patient initials (F,M,L) and the first three letters of the month (e.g.: JAN)

Consultation on contraception	**Tick**	
Does the patient need a referral for contraceptive counselling?	Yes ☐	No ☐
Was patient referred to a contraceptive consultant, if required?	Yes ☐	No ☐
Has the patient been consulted about contraceptive methods?	Yes ☐	No ☐
If yes, counselling date	dd.mm.yyyy	
Has the patient been established on contraception for at least 4 weeks?	Yes ☐	No ☐
Is the patient capable of complying with contraceptive measures?	Yes ☐	No ☐

Contraception method	**Tick**
Implant	☐
Levonorgestrel-releasing intrauterine system (IUS)	☐
Medroxyprogesterone acetate depot	☐
Tubal sterilization	☐
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)	☐
Abstinence (committed to absolute and continuous abstinence)	☐

Pregnancy testing	**Tick**	
Had patient a negative pregnancy test before starting treatment even if absolute and continued abstinence?	Yes ☐	No ☐
Pregnancy test date:		

Lenalidomide treatment cannot start until the patient has been established on at least one effective method of contraception for 4 weeks, or commits to complete and continuous abstinence, and obtains a negative pregnancy test.

Prescriber Confirmation/Agreement

I have fully informed the above-named patient about their lenalidomide treatment, its purpose of use, and any potential health risks associated with lenalidomide treatment, including the risks to women of childbearing potential. I will comply with my obligations and responsibilities as a prescriber of lenalidomide therapy.

Physicians name, surname:	Signature:	Date (dd/mmm/yyyy):

To be completed by the patient

Read carefully and tick in the box near the statement if you agree with it

	Tick
I understand that lenalidomide is expected to cause severe life-threatening birth defects. 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.	☐
I understand that I must not take lenalidomide if I am pregnant or plan to become pregnant.	☐
I understand that I must use at least one effective method of contraception without interruption, for at least 4 weeks before starting treatment, throughout the entire duration of treatment and even in case of dose interruptions, and for at least 4 weeks after the end of treatment or commit to absolute and continuous sexual abstinence confirmed on a monthly basis. An effective method of contraception must be initiated by an appropriately trained healthcare professional.	☐
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 and the physician prescribing my lenalidomide.	☐
I understand that before starting lenalidomide treatment I must have a medically supervised pregnancy test. Unless it is confirmed I have had a tubal sterilisation I will then have a pregnancy test every 4 weeks during treatment, and a test at least 4 weeks after the end of treatment.	☐
I understand that I must immediately stop taking lenalidomide and inform my treating doctor immediately upon suspicion of pregnancy while taking this drug (including dose interruptions); or if I miss my menstrual period or experience any unusual menstrual bleeding; or think FOR ANY REASON that I may be pregnant.	☐
I understand that even if I have amenorrhoea I must comply with advice on contraception.	☐
I am informed about the risk of thromboembolism and the possible antithrombotic prophylactic measures during treatment with lenalidomide.	☐
I have read the lenalidomide Patient Brochure and understand the contents, including the information about other possible important health problems related to lenalidomide.	☐
I know that I cannot donate blood while taking lenalidomide (including dose interruptions) or for 7 days after stopping treatment.	☐
I understand that lenalidomide will be prescribed ONLY for me. I must not share it with ANYONE.	☐
I understand that I must return any unused lenalidomide capsules to my pharmacy at the end of my treatment.	☐
I am informed that I must receive the medicine at the pharmacy within 7 days after it is prescribed.	☐

Patient confirmation

□ 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.

□ I agree that my healthcare provider (physician or pharmacist) will use my personal data as part of the Pregnancy Prevention Programme.

I confirm and give my explicitly consent to the transfer of my personal data to the Marketing Authorization Holder of lenalidomide, its affiliates and partners, which may be located in other countries, the National Competent Authority and to the Medicines Agencies in other countries.

I know that before transfer of my personal information, my name or any other information that would allow me to be identified will be replaced by a code.

□ I have read the terms of the data processing and agree that my personal data is being processed.

The manufacturer and healthcare providers will take appropriate measures to ensure that your information is appropriately stored in accordance with General Data Protection Regulation (GDPR).

You have the right to withdraw your consent to the processing of personal data at any time. Withdrawal of consent does not affect the lawfulness of the processing based on consent prior to the withdrawal. The data subject was informed prior to consent.

Signature	**Date (dd/mmm/yyyy):**

Lenalidomide Grindeks

Pregnancy Prevention Programme

Woman of non-childbearing potential

Risk awareness form

This Risk awareness form must be completed for each patient before starting therapy with lenalidomide.

It is mandatory that each patient receive counselling and education to be made aware of the risks of lenalidomide.

The aim of this Risk awareness form is to protect patients and any possible foetuses by ensuring that patients are fully aware of and understand the risk of teratogenicity and other adverse effects associated with the use of lenalidomide.

It is mandatory that woman of non-childbearing potential receive counselling and education to be made aware of the risks of lenalidomide.

This Risk awareness form must be kept with patient's medical records and a copy provided to the patient.

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 information

Patient First Name:	
Patient Last Name:	
Date of Birth:	
Patient code[2]/initials:	
Counselling Date:	

Criteria that determine patient is woman NOT of childbearing potential	**Tick**
Age ≥ 50 years and naturally amenorrhoeic for ≥ 1 year (Amenorrhoea following cancer therapy or during breast-feeding 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	☐

You must inform your patient:	***Woman of non-childbearing potential*** **Tick**
Of the high teratogenic potential of lenalidomide.	☐
About the risk of thromboembolism and the possible antithrombotic prophylactic measures during treatment with lenalidomide	☐
About other serious side effects of lenalidomide (please give Patient Brochure to the patient).	☐
Not to donate blood during therapy or for 7 days following discontinuation of lenalidomide	☐
Not to share medication with any other person.	☐
To return unused capsules to pharmacist at the end of treatment.	☐

[2] Please use patient initials (F,M,L) and the first three letters of the month (e.g.: JAN)

Prescriber Confirmation/Agreement

I have fully informed the above-named patient about their lenalidomide treatment, its purpose of use, and any potential health risks associated with lenalidomide treatment, including the risks to women of childbearing potential.
I will comply with my obligations and responsibilities as a prescriber of lenalidomide therapy.

Physicians name, surname:	Signature:	Date (dd/mmm/yyyy):

To be completed by the patient

Read carefully and tick in the box near the statement if you agree with it

	Tick
I understand that lenalidomide is expected to cause severe life-threatening birth defects. 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.	☐
I am informed about the risk of thromboembolism and the possible antithrombotic prophylactic measures during treatment with lenalidomide.	☐
I have read the lenalidomide Patient brochure and understand the contents, including the information about other possible important health problems (side effects) related to lenalidomide.	☐
I know that I cannot donate blood while taking pomalidomdie (including dose interruptions) or for 7 days after stopping treatment.	☐
I understand that lenalidomide will be prescribed ONLY for me. I must not share it with ANYONE.	☐
I understand that I must return any unused lenalidomide capsules to my pharmacy at the end of my treatment.	☐

Patient confirmation

□ 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.

□ I agree that my healthcare provider (physician or pharmacist) will use my personal data as part of the Pregnancy Prevention Programme.

I confirm and give my explicitly consent to the transfer of my personal data to the Marketing Authorization Holder of lenalidomide, its affiliates and partners, which may be located in other countries, the National Competent Authority and to the Medicines Agencies in other countries.

I know that before transfer of my personal information, my name or any other information that would allow me to be identified will be replaced by a code.

□ I have read the terms of the data processing and agree that my personal data is being processed.

The manufacturer and healthcare providers will take appropriate measures to ensure that your information is appropriately stored in accordance with General Data Protection Regulation (GDPR).

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Signature:	**Date (dd/mmm/yyyy):**

Lenalidomide Grindeks

Pregnancy Prevention Programme

Male

Risk awareness form

This Risk awareness form must be completed for each patient before starting therapy with lenalidomide.

It is mandatory that each patient receive counselling and education to be made aware of the risks of lenalidomide.

The aim of this Risk awareness form is to protect patients and any possible foetuses by ensuring that patients are fully aware of and understand the risk of teratogenicity and other adverse effects 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 Risk awareness form must be kept with patient's medical records and a copy provided to the patient.

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 information

Patient First Name:	
Patient Last Name:	
Date of Birth:	
Patient code[3]/initials:	
Counselling Date:	

You must inform your patient:	***Male*** **Tick**
Of the high teratogenic potential of lenalidomide and the need to inform his treating physician immediately and the need refer the female partner to a physician experienced in teratology if his female partner becomes pregnant or is pregnant whilst he is taking lenalidomide.	☐
Of the need for the use of a condom if engaged in sexual activity with a pregnant woman or a woman of childbearing potential not using effective contraception (even if the man has had a vasectomy), during treatment and for 7 days after dose interruptions and/or cessation of treatment	☐
About the risk of thromboembolism and the possible antithrombotic prophylactic measures during treatment with lenalidomide	☐
About other serious side effects of lenalidomide (please give *Patient Brochure* to the patient)	☐
Not to donate blood or semen during therapy (including dose interruptions) or for 7 days following discontinuation of lenalidomide	☐
Not to share medication with any other person.	☐
To return unused capsules to pharmacist at the end of treatment.	☐
Confirm patient is capable of complying with contraceptive measures	☐

Pregnancy Prevention

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

Prescriber Confirmation/Agreement

I have fully informed the above-named patient about their lenalidomide treatment, its purpose of use, and any potential health risks associated with lenalidomide treatment, including the risks to women of childbearing potential.
I will comply with my obligations and responsibilities as a prescriber of lenalidomide therapy.

Physicians name, surname:	Signature:	Date (dd/mmm/yyyy):

[3] Please use patient initials (F,M,L) and the first three letters of the month (e.g.: JAN)

To be completed by the patient

Read carefully and tick in the box near the statement if you agree with it

	Tick
I understand that lenalidomide is expected to cause severe birth defects in unborn child if a woman is pregnant or becomes pregnant whilst taking it.	☐
I understand that lenalidomide passes into human semen. If my partner is pregnant or is a woman of childbearing potential who is not using effective contraception, I agree to use condoms during sexual activity throughout treatment duration, during dose interruption, and for 7 days after cessation of treatment even if I have had a vasectomy.	☐
I know that I must inform my doctor 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 referred to a physician specialized or experienced in teratology for evaluation and advice.	☐
I have been informed about effective methods of contraception that my female partner can use.	☐
I am informed about the risk of thromboembolism and the possible antithrombotic prophylactic measures during treatment with lenalidomide.	☐
I have read the lenalidomide *Patient Brochure* and understand the contents, including the information about other possible important health problems (side effects) related to lenalidomide.	☐
I understand that I cannot donate blood or semen during treatment while taking lenalidomide (including dose interruptions) or for 7 days after stopping treatment.	☐
I understand that lenalidomide will be prescribed ONLY for me. I must not share it with ANYONE.	☐
I understand that I must return any unused lenalidomide capsules to my pharmacy at the end of my treatment.	☐

Patient confirmation

☐ 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.

☐ I agree that my healthcare provider (physician or pharmacist) will use my personal data as part of the Pregnancy Prevention Programme.

I confirm and give my explicitly consent to the transfer of my personal data to the Marketing Authorization Holder of lenalidomide, its affiliates and partners, which may be located in other countries, the National Competent Authority and to the Medicines Agencies in other countries.

I know that before transfer of my personal information, my name or any other information that would allow me to be identified will be replaced by a code.

☐ I have read the terms of the data processing and agree that my personal data is being processed.

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You have the right to withdraw your consent to the processing of personal data at any time. Withdrawal of consent does not affect the lawfulness of the processing based on consent prior to the withdrawal. The data subject was informed prior to consent.

Signature	**Date (dd/mmm/yyyy):**