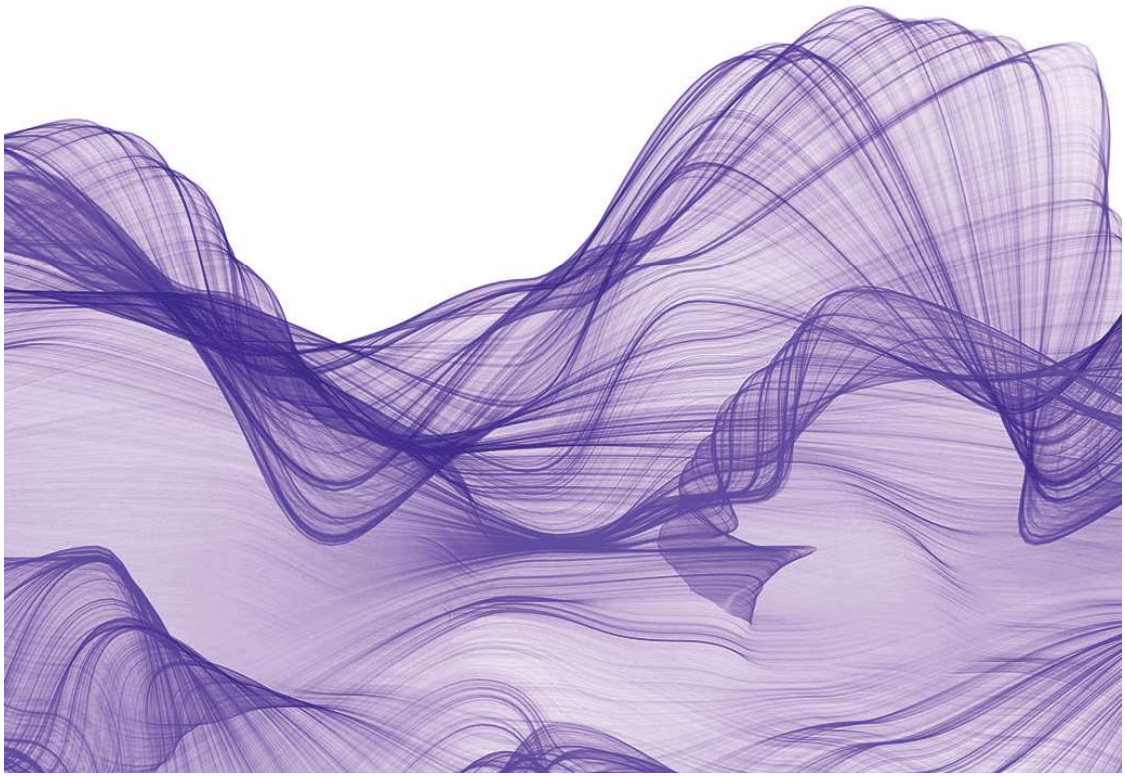
K.S. KIM INTERNATIONAL

Patient Information Booklet

Lenalidomide S.K.

RMP- Risk Management Plan

PPP- Pregnancy Prevention Program



Contents

Lenalidomide S.K. was found to be harmful to foetuses or cause birth defects in animals and is likely to have similar effects in humans.

Your doctor has registered you to a Risk Management Plan (RMP), Pregnancy Prevention Program (PPP).

The aim of this program is to assist your doctor to inform you regarding the risks related to an unborn child associated with Lenalidomide S.K. treatment and to ensure that you are aware of the precautions you need to take before, during and after the treatment.

You must understand and consent to the program conditions to receive the treatment with Lenalidomide S.K.

Disclaimer: This information pack **only** refers to Risk Management Plan (RMP), Pregnancy Prevention Program (PPP). To find out more about the medication, side-effects and warnings please speak with your healthcare professional and read the patient information leaflet.

Personal Information

Information for patients, doctors, caregivers & pharmacists about the use of personal information – risk management program relating to the administration of the drug Lenalidomide

K.S. Kim International Ltd. (hereinafter: "K.S. Kim" or "we") respects your right to privacy. Your ability to make informed decisions about the use of information belonging to you is important to us. In this document, we specify the information that we collect from you, how we protect it and what uses we make of the information.

Information that we collect

"Personal information" is information that can be attributed to a person or entity, such as a name, address or medical information. The personal information that we collect from patients includes name/ initials, identity card number (or other identification number), date of birth, membership in an HMO, medical condition and diagnosis, state of pregnancy and/or fertility, the type of treatment and medicines, details about parents and/or guardians and/or participation in instructional sessions. It is your voluntary decision whether or not to provide us with particular information, but we must collect and retain some of the information in order to comply with the statutory and regulatory requirements.

How we protect the information

We employ commercially reasonable measures to protect the information furnished to us, but there are no electronic transfer or storage methods that are absolutely secure. Therefore, although we try to employ maximum measures to protect your information, we cannot guarantee the absolute security of the information.

How we use the information

We will not share your information with any other parties without your express consent, apart from in ways explicitly referred to here, unless we will be required to do so pursuant to any law, regulation or court order or for the purpose of cooperating with an investigation by the law enforcement authorities. The main purpose for collecting and saving the information about you is to participate in risk management programs as is required by law and regulation. We will share the information with the authorized authorities for the purpose of complying with these requirements.

We use an external company as a subcontractor in order to provide us with services relating to the personal information, including in order to participate in a risk management program, and in order to store the personal information on their servers. All of the subcontractors will be subject to nondisclosure and non-use of information obligations. We might transfer our databases, which contain your information, if we sell our business or a portion thereof, including while negotiating the sale and including during liquidation.

Right to peruse and amend

You have a right to demand to peruse your information or to update or correct it. If you wish to do so, please contact us at lenalidomide@sk-pharma.com. If you have any questions about this privacy policy, if you do not agree to that stated therein or if you wish to contact us about any other matter, please contact us at lenalidomide@sk-pharma.com.

I have read the document "Information for patients, doctors, caregivers & pharmacists about the use of personal information – risk management program relating to the administration of the drug Lenalidomide" and I agree to that stated therein.

Summary

- Lenalidomide S.K. is expected to be harmful to a foetus.
- Lenalidomide S.K. must never be taken by a woman who is pregnant or who could become pregnant.
- If Lenalidomide S.K. is taken during pregnancy, severe, life-threatening birth defects are expected
- Women of reproductive potential must commit either to abstain continuously from heterosexual sexual intercourse or to use 2 methods of reliable birth control simultaneously
- Lenalidomide S.K. is expected to be harmful to breastfed children, therefore women should not breastfeed during treatment with Lenalidomide S.K.
- Men taking Lenalidomide S.K. must use a condom during sexual contact with pregnant women or a woman who is able to become pregnant whilst he is taking Lenalidomide S.K. until 4 weeks after stopping treatment.
    - Male patients must always use a condom during any sexual contact with females of reproductive potential while taking Lenalidomide S.K. and for up to 4 weeks after discontinuing Lenalidomide S.K., even if they have undergone a successful vasectomy.
    - Contraception should be started by the patient's partner at least 4 weeks prior to the start of a sexual relationship with the patient and continued throughout Lenalidomide S.K. therapy including dose interruptions and **for 4 weeks following discontinuation of therapy.**

If you suspect that you or your partner is pregnant, you must URGENTLY contact your doctor.

① **<u>You must never take Lenalidomide S.K. if:</u>**

- Do not take Lenalidomide S.K. if you are pregnant or if you are planning to get pregnant
- Do not take Lenalidomide S.K. if you are breastfeeding
    - Do not breastfeed during the treatment
    - Do not breastfeed until at least 4 weeks after stopping treatment
- Do not take Lenalidomide S.K. if you can get pregnant:
    - If you are able to become pregnant or a woman of childbearing potential, **even if you are not planning to become pregnant** you must use at least two reliable contraceptives; this will be discussed with your doctor and you must wait for 4 weeks after the end of treatment with the medicine before attempting to get pregnant
- Do not take Lenalidomide S.K. if you are sensitive (allergic) to lenalidomide or to any of the other ingredients of this medicine (listed in section 6 of patient leaflet)
- Do not donate blood, semen or sperm during the treatment with Lenalidomide S.K., during treatment interruptions and for 4 weeks after treatment discontinuation.

②**Information for women who are able to become pregnant**

If you are pregnant, if you think you may be pregnant or if you are planning to become pregnant **you must not** take Lenalidomide S.K.

Some women who are not having regular periods or who are approaching the menopause may still be able to become pregnant

For patients of childbearing potential;

- **Two effective contraception methods** must be used by female patients of childbearing potential:
    1. **One** highly effective form of contraception – tubal ligation, IUD, hormonal (birth control pills, injections, hormonal patches, vaginal rings, or implants), or partner's vasectomy,
    2. **Plus** one additional effective contraceptive method – male latex or synthetic condom, diaphragm, or cervical cap.
- Unless **continuous abstinence** from heterosexual sexual contact is the chosen method

For:

- at least 4 weeks before starting Lenalidomide S.K. treatment,
- **during** Lenalidomide S.K. treatment,
- **during** any breaks in Lenalidomide S.K. treatment; and
- **for** 4 weeks after stopping Lenalidomide S.K. treatment.

- You and your partner should discuss with your doctor suitable forms of contraception that you both find acceptable.
- You should start your Lenalidomide S.K. treatment as soon as possible after having a negative pregnancy test result.

If for any reason you think you may be pregnant while you are taking Lenalidomide S.K., or in the 4 weeks after stopping, you must immediately stop taking Lenalidomide S.K. and contact your doctor.

Pregnancy tests to ensure you are not pregnant

If you are a woman who could become pregnant you must have a pregnancy test, overseen by your doctor, to make sure you are not pregnant:

The pregnancy tests should be performed prior to beginning therapy within 3 days before your doctor prescribes Lenalidomide S.K. and then monthly thereafter.

Each prescription for Lenalidomide S.K. will **only** be dispensed with confirmation by your doctor that you are not pregnant using "Monthly Pregnancy Test Form" this is to ensure that an unborn baby is not exposed to Lenalidomide S.K.

You must provide the pregnancy test results with the prescription. The prescription will only be issued within 3 days from negative pregnancy test.

③**Information for women who are not able to become pregnant**

Before starting Lenalidomide S.K. treatment you should discuss with your doctor whether there is any possibility that you could become pregnant.

Unless you fall into one of the following categories you must follow the pregnancy prevention advice presented in section 2:

- It has been at least 24 months since your last period (if your periods have stopped because of cancer therapy, then there is still a chance you could become pregnant)
- Your womb has been removed (hysterectomy)
- Both of your ovaries have been removed (bilateral oophorectomy)
- Any other case determined by a doctor

Every woman who is able to become pregnant even if they are not planning to must follow the precautions detailed in section 2 'Information for women who are able to become pregnant'.

To ensure that an unborn baby is not exposed to Lenalidomide S.K., your doctor will need to complete "Monthly Pregnancy Test Form" with each prescription. **Unless** you have exemption confirmation from you doctor.

④**Information for men**

Lenalidomide S.K. passes into human semen:

- You must use a condom every time you have sexual contact with a woman who is pregnant **or** able to become pregnant.
- **Even if you have had a vasectomy** you must use a condom throughout your Lenalidomide S.K. treatment, during any breaks in treatment and for 4 weeks after stopping treatment.
- In you have an allergy to latex or polyurethane, at least one highly effective form of contraception should be used by any female sexual partner
    - Contraception should be started in this partner at least 4 weeks prior to the start of a sexual relationship with the patient,
    - continued throughout treatment including dose interruptions, and
    - for 4 weeks following discontinuation of treatment.
- You should not donate blood and semen or sperm during treatment, during any breaks, and for 4 weeks following discontinuation Lenalidomide S.K.

If your partner does become pregnant while you are taking Lenalidomide S.K., you must contact your doctor immediately, and your partner should also inform her doctor immediately.

⑤**Pregnancy Prevention Program Initiation & Reports**

The following conditions must be met to receive the treatment:

1. ☐ Your doctor prescribing the treatment is registered in the Risk Management Program

2. ☐ The pharmacy dispensing your prescription must be registered in the Risk Management Program

3. ☐ Your doctor must register you to the Risk Management Program, this includes explaining the program and obtaining your consent to all the requirements

4. ☐ Patients below the age of 18 will be registered by approval of their legal guardian only

⑥Prescription information

A prescription will be given for a period of 4 weeks only.

For each prescription, all the conditions mentioned in this booklet will be checked. If the conditions are not all met, the medicine will not be supplied.

You must ensure that you receive your Lenalidomide S.K., from your pharmacy, within 7 days of it being prescribed or you will need a new prescription

If you are a woman of childbearing potential, the doctor must verify that a negative pregnancy test is available before issuing the prescription (Provide the test results with the prescription. The test results should be from a date no earlier than 3 days prior to issuing the prescription).

Lenalidomide S.K. has been prescribed for the treatment of your disease. Do not pass it to others. It may harm them even if it seems to you that their medical condition is similar. Return any unused capsules to the pharmacy.

The consent form documents that you have given consent for Lenalidomide S.K. treatment and have been told about the risks to an unborn baby and the precautions you must take.

⑦**End of Treatment Requirements**

After completing your Lenalidomide S.K. treatment, it is important that:

You return any unused Lenalidomide S.K. capsules to your pharmacist

You do not donate blood for 4 weeks.

Additional advice for women who are able to become pregnant:

Continue using your effective pregnancy prevention method for a further 4 weeks.

Your doctor will perform a final pregnancy test 4 weeks after stopping treatment.

Additional advice for male patients:

If you have been using an effective pregnancy prevention method, you must continue doing so for 4 weeks following discontinuation of Lenalidomide S.K.

If your female partner has been using an effective pregnancy prevention method, she must continue doing so for 4 weeks.

You should not donate blood, semen or sperm during treatment, during any breaks, and for 4 weeks following discontinuation Lenalidomide S.K.

⑧Additional information

What is Lenalidomide S.K.?

Lenalidomide S.K. contains the active substance 'lenalidomide'. This medicine belongs to a group of medicines which affect how your immune system works.

Lenalidomide S.K. works by affecting the body's immune system and directly attacking the cancer.

It works in a number of different ways:

- by stopping the cancer cells developing
- by stopping blood vessels growing in the cancer
- by stimulating part of the immune system to attack the cancer cells.

Lenalidomide S.K. is structurally related to thalidomide, which is known to cause severe, life-threatening birth defects. Precautions must be taken to avoid exposure to Lenalidomide S.K. in an unborn baby.

Lenalidomide S.K. can increase the number of red blood cells produced by the body by reducing the number of abnormal cells. The treatment can lead to reduction of the number of required blood units.

Lenalidomide S.K. is used for:

- The maintenance treatment of adult patients with newly diagnosed **multiple myeloma** (MM) who have undergone autologous stem cell transplantation.

- Previously untreated **multiple myeloma** in adult patients who are not eligible for transplant.

- In combination with dexamethasone treatment of **multiple myeloma** patients who have received at least one prior therapy.

- Patients with transfusion-dependent anaemia due to low- or intermediate-1-risk **myelodysplastic syndromes (MDS)** associated with a deletion 5q cytogenetic abnormality with or without additional cytogenetic abnormalities.

- Lenalidomide S.K. 7.5 mg is **not indicated** for treatment in **MDS**.

- The treatment of adult patients with relapsed and/or refractory **mantle cell lymphoma (MCL).**

Reports on pregnancy or side effects during treatment with Lenalidomide S.K. should be sent to the following parties:

To the Ministry of Health

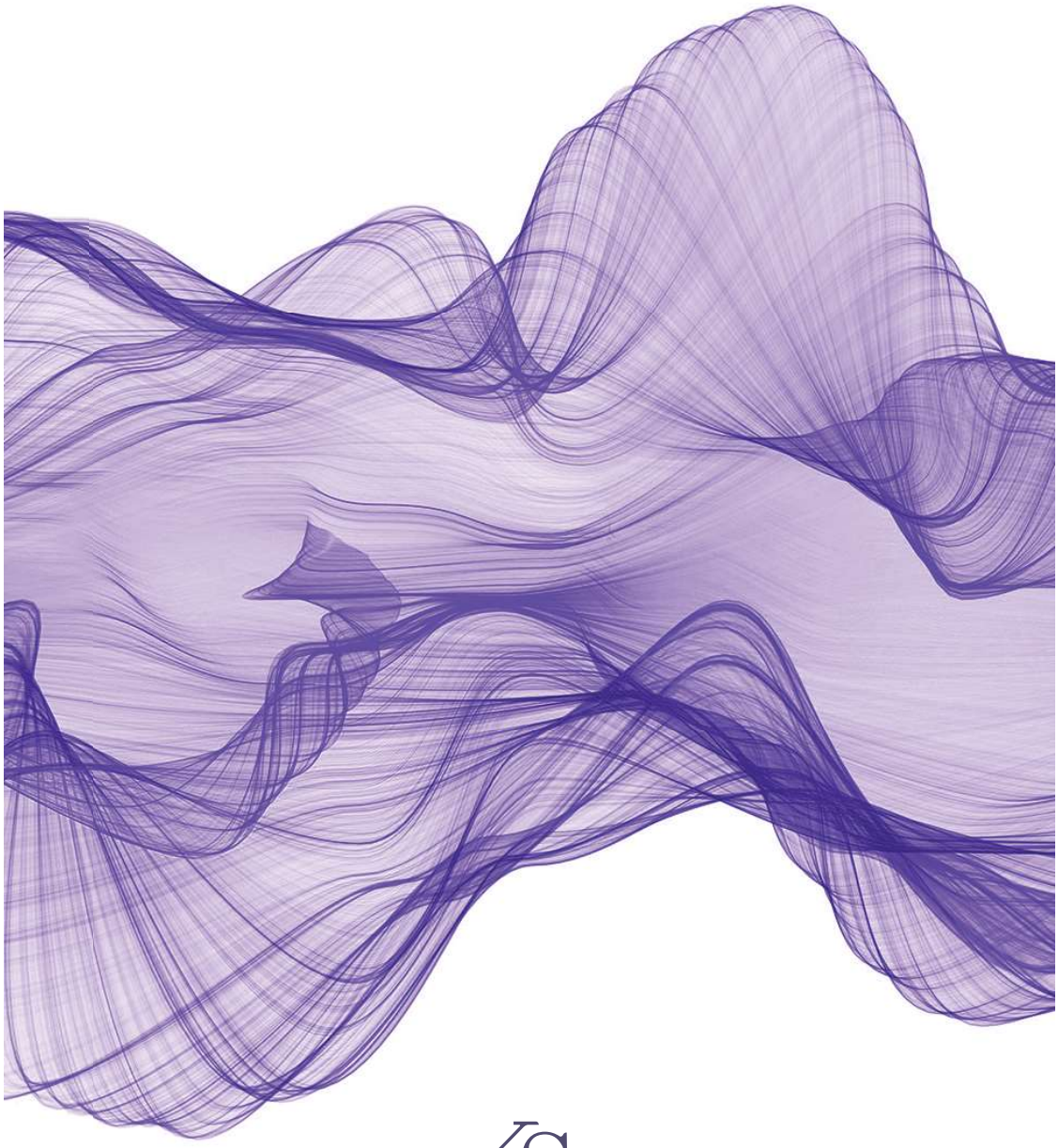
Use the portal of side effects reporting the Ministry of Health:

https://sideeffects.health.gov.il/

To K.S. Kim International Ltd.

- lenalidomide@sk-pharma.com
- 03-611-4543

For further information, read the entire patient information leaflet carefully before using the medicine. If you have further questions, contact the doctor or pharmacist.



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