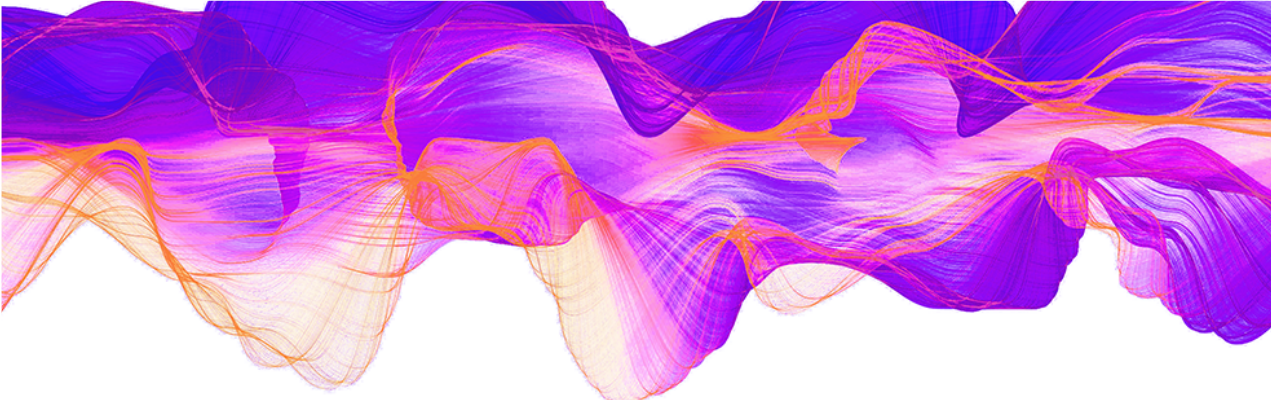




Information for Healthcare Professionals

Lenalidomide S.K. (Lenalidomide)

RMP- Risk Management Plan
PPP- Pregnancy Prevention Program



Lenalidomide S.K Information for Healthcare Professionals

Prescribing or Dispensing Lenalidomide S.K

This brochure contains the information needed for prescribing and dispensing Lenalidomide S.K., including information about the Pregnancy Prevention Programme (PPP).

Please also refer to the Summary of Product Characteristics (SmPC), for further information.

Lenalidomide S.K. Pregnancy Prevention Programme:

If Lenalidomide is taken during pregnancy, it can cause severe birth defects 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, the controlled distribution and explain your responsibilities to make sure you know what to do before prescribing and dispensing Lenalidomide S.K..

For your patients' health and safety, please read this brochure carefully. You must ensure that your patients fully understand what you have told them about Lenalidomide S.K. and that they have provided written confirmation on the patient registration form, before starting treatment.

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Please note: additional educational materials and forms of the program (not included in this brochure):

- Patient Educational Materials (brochures in Hebrew, Arabic, Russian and English)
- **Program Registration Forms for:**
 - Physician
 - Pharmacy
 - Patient- to be filled-in by the physician and signed by the physician and patient (patient section is available in Hebrew, Arabic, Russian and English)
- **Pregnancy Reporting Form**
- **Pregnancy Test Results Form**

For full information please refer to Lenalidomide SmPC as approved by IL MOH

1. About Lenalidomide S.K.:

Lenalidomide S.K. is indicated for:

- **Multiple Myeloma (MM)**
- **Myelodysplastic Syndromes (MSD)**
Lenalidomide S.K. is indicated for patients with transfusion-dependent anemia 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.
- **Mantle Cell Lymphoma (MCL)**
Lenalidomide S.K. is indicated for the treatment of adult patients with relapsed and/or refractory mantle cell lymphoma (MCL).
- **Follicular lymphoma (FL)**
Lenalidomide S.K. in combination with rituximab (anti-CD20 antibody) is indicated for the treatment of adult patients with previously treated follicular lymphoma.

2. The Teratogenicity of Lenalidomide S.K.

Lenalidomide S.K. must not be taken during pregnancy, since a teratogenic effect is expected.

Lenalidomide is structurally related to Thalidomide. Thalidomide is a known human teratogenic substance that causes severe life-threatening birth defects. An embryofoetal development study has been conducted in monkeys administered with Lenalidomide at doses up to 4mg/kg/day. Findings from this study showed that Lenalidomide produced external malformations (short limbs, bent digits, wrist and/ or tail, supernumerary or absent digits) in the offspring of female monkeys who received the drug during pregnancy. Thalidomide produced similar types of malformations in the same study. If Lenalidomide is taken during pregnancy, a teratogenic effect in humans is expected. Lenalidomide is therefore contraindicated in pregnancy and in women of childbearing potential unless the conditions of the Pregnancy Prevention Programme described in this HCP brochure are met.

3. Obligations of the Healthcare Professional in Relation to the Prescribing and Dispensing of Lenalidomide S.K.

Special Prescribing Requirements

Lenalidomide S.K. Pregnancy Prevention Programme and controlled distribution program

Due to the potential toxicity of Lenalidomide and to avoid fetal exposure, Lenalidomide S.K. is only available under a special controlled distribution program. Prescribers and pharmacists registered with the program can prescribe and dispense the product to patients who are registered and meet all the conditions of the Pregnancy Prevention Programme.

Please see the following information about the controlled distribution program for prescribers, pharmacists, female patients, and male patients.

The conditions of the Pregnancy Prevention Program must be fulfilled for all patients, **males and females**, unless there is reliable evidence that the patient does not have childbearing potential.

Prescriber: You must ensure that

- You provide comprehensive advice and counselling to patients.
- Women of childbearing potential (patients or patients' partners):
 - The woman complies with the conditions of the Pregnancy Prevention Program, including confirmation that she has an adequate level of understanding.
 - The woman has acknowledged the aforementioned conditions.
- You provide patients with appropriate patient educational brochure.
- You explain that the maximum duration of a prescription for women of childbearing potential is **4 weeks**, and prescriptions for all other patients can be for a maximum duration of **12 weeks**.

Pharmacist: You must ensure that

- Your pharmacy is registered with the Lenalidomide S.K. Pregnancy Prevention Programme.
- **Lenalidomide S.K. is only dispensed if the prescription is accompanied by dispensing approval number provided by S.K. Pharma.**
- You dispense Lenalidomide S.K. in accordance with the measures described in this brochure.
- You remind patients of key education messages each time Lenalidomide S.K. is dispensed.

4. Criteria for women of non-childbearing potential

A female patient or a female partner of a male patient is considered to have childbearing potential unless she meets at least one of the following criteria:

- Age $\geq$ 50 years and naturally amenorrhoeic for $\geq$ 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

Please refer your patient for a gynecological opinion if you are unsure whether or not she meets these criteria.

5. Counselling

5.1 Safety advice for Women of Childbearing Potential:

For women of childbearing potential, **Lenalidomide S.K. is contraindicated unless all of the following are met:**

- ☑ She was explained the expected teratogenic risk to the unborn child.
- ☑ She was explained the need for 2 two reliable contraceptive methods, without interruption, 4 weeks before starting treatment, throughout the entire duration of treatment, and 4 weeks at least after the end of treatment (unless absolute and continuous sexual abstinence confirmed on monthly basis).
- ☑ Even if a woman of childbearing potential has amenorrhea, she must follow all the advice on effective contraception.
- ☑ She should be capable of complying with effective contraceptive measures (use simultaneously two reliable methods of contraception as described in “Contraception” section and SmPC).
- ☑ She was explained that once established on contraception for 4 weeks the patient is required to have a medically supervised negative pregnancy test (with a minimum sensitivity of 25 mIU/ml). The first prescription for Lenalidomide S.K. can only be given after one negative medically supervised pregnancy test.
- ☑ She was explained the need to commence the treatment as soon as Lenalidomide S.K. is dispensed following a negative pregnancy test.
- ☑ She was explained the need and accepts to undergo pregnancy testing every 4 weeks. This includes those women of childbearing potential who confirm absolute and continued abstinence.
- ☑ She was explained that the test results should be from a date no earlier than 3 days prior to issuing the prescription and ideally, pregnancy testing, issuing a prescription and dispensing should occur on the same day. **Dispensing of Lenalidomide S.K. to women of childbearing potential should occur within 7 days of the prescription and following a medically supervised negative pregnancy test result.**
- ☑ She is informed and understands the potential consequences of pregnancy and the need to rapidly consult if there is a risk of pregnancy.
- ☑ She was advised to inform you if a change or stop of method of contraception is needed.
- ☑ She was explained that the maximum duration of a prescription is 4 weeks.
- ☑ She was explained that she can not donate blood during treatment, during dose interruptions, or for at least 4 weeks after stopping treatment.
- ☑ She was explained that she should never share Lenalidomide S.K. with anyone else, and that she should always return any unused capsules to the pharmacist for safe disposal as soon as possible.
- ☑ She acknowledges that she was explained the hazards and necessary precautions associated with the use of Lenalidomide S.K.
- ☑ If she becomes pregnant whilst taking Lenalidomide S.K., she must stop therapy and inform her treating physician immediately. It is recommended to refer the patient to a physician specialised or experienced in teratology for evaluation and advice.
- ☑ She was explained that after completing use of the medicine, she should wait at least 4 more weeks before trying to become pregnant.

5.2 Safety advice for Women of Non Childbearing Potential

In order to ensure that an unborn baby is not exposed to Pomalidomide, the prescriber will ensure that the patient is not a women of childbearing potential according to the criteria elaborated in section “Criteria for women of non-childbearing potential”.

Prescribers are advised to refer their patient for a gynecological opinion if unsure as to whether a woman meets the criteria for being of non-childbearing potential.

Inform your patient with the following:

- ☑ She should never share Lenalidomide S.K. with anyone else, and that she should always return any unused capsules to the pharmacist for safe disposal as soon as possible.
- ☑ She can not donate blood during treatment, during dose interruptions, or for at least 4 weeks after stopping treatment.
- ☑ The maximum duration of a prescription is 12 weeks.

5.3 Safety advice for men

Clinical data has demonstrated the presence of Lenalidomide in human semen.

For male patients taking Lenalidomide S.K., in view of the expected teratogenic risk of Lenalidomide, foetal exposure should be avoided.

Inform your patient with the following:

- ☑ The expected teratogenic risk if engaged in sexual activity with a pregnant woman or a woman of childbearing potential.
- ☑ Lenalidomide is present in human semen during treatment. As a precaution, and taking into account special populations with potentially prolonged elimination time such as hepatic impairment, all male patients taking Lenalidomide, including those who have had a vasectomy as seminal fluid may still contain Lenalidomide in the absence of spermatozoa, should use condoms throughout treatment duration, during dose interruption and for at least 4 weeks after cessation of treatment if their partner is pregnant or of child bearing potential and has no contraception.
- ☑ Which are the effective contraceptive methods that his female partner can use.
- ☑ He should not donate blood, semen or sperm during treatment (including during dose interruptions) and for at least 4 weeks following discontinuation of Lenalidomide.
- ☑ If his partner becomes pregnant whilst he is taking Lenalidomide or 4 weeks after he has stopped taking Lenalidomide he should inform his treating physician immediately. The partner should inform her physician immediately. It is recommended that she is referred to a physician specialised in teratology for evaluation and advice.
- ☑ He should never share Lenalidomide S.K. with anyone else, and he should always return any unused capsules to the pharmacist for safe disposal as soon as possible.
- ☑ The maximum duration of a prescription is 12 weeks.

6. Contraception

Women of childbearing potential must use two effective methods of contraception for at least 4 weeks before therapy, during therapy, and until at least 4 weeks after Lenalidomide S.K. therapy and even in case of dose interruption, unless the patient commits to absolute and continuous abstinence confirmed on a monthly basis.

Contraceptive methods must include at least 1 highly effective method AND 1 additional effective barrier method.

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 highly effective suitable contraceptive methods of contraception:

- 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)

The following are Additional effective barrier methods:

- Condom
- Diaphragm
- Cervical cap

Because of the increased risk of venous thromboembolism in patients with multiple myeloma taking Lenalidomide and Dexamethasone, combined oral contraceptive pills are not recommended. If a patient is currently using combined oral contraceptive pills the patient should switch to one of the highly effective methods listed above. The risk of venous thromboembolism continues for 4–6 weeks after discontinuing combined oral contraception. The efficacy of contraceptive steroids may be reduced during cotreatment 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 is not recommended due to the potential risks of infection at the time of insertion and menstrual blood loss which may compromise patients with severe neutropenia or severe thrombocytopenia.

7. Pregnancy Testing

For women of childbearing potential a pregnancy test must be performed prior to the dispensing of each prescription of Lenalidomide S.K..

- A pregnancy test is required even if the patient has not had heterosexual intercourse since her last pregnancy test.
- According to local practice, medically supervised pregnancy tests with a minimum sensitivity of 25 mIU/mL must be performed for women of childbearing potential.
- The test results should be from a date no earlier than 3 days prior to issuing the prescription and ideally, pregnancy testing, issuing a prescription and dispensing should occur on the same day.
- Dispensing of Lenalidomide S.K. to women of childbearing potential should occur within 7 days of the prescription.

7.1 Prior to starting treatment

A medically supervised pregnancy test should be performed during the consultation, when Lenalidomide S.K. is prescribed, or in the 3 days prior to the visit to the prescriber, once the patient had been using 2 effective contraception methods for at least 4 weeks (contraception is needed unless the patient commits to absolute and continuous sexual abstinence confirmed on monthly basis). The test should ensure the patient is not pregnant when she starts treatment with Lenalidomide S.K..

7.2 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.

7.3 Requirements in the event of pregnancy

Upon suspicion of pregnancy during Lenalidomide S.K. therapy (or within 4 weeks from stopping treatment), the prescriber should inform S.K. Pharma immediately. The pregnancy report (while on Lenalidomide S.K. therapy) should be provided by filling-in the Pregnancy reporting form.

8. Educational materials, prescribing and dispensing restrictions

In order to assist patients in avoiding foetal exposure to Lenalidomide S.K., the marketing authorization holder will provide educational material to healthcare

professionals to reinforce the warnings about the expected teratogenicity of Lenalidomide S.K., 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. A national controlled distribution system has been implemented in collaboration with the Ministry of Health. The controlled distribution system includes the use of a patient brochure, a prescribing and healthcare professional brochure and dispensing controls.

9. Safety Advice Relevant to all Parties:

The following section contains advice to Healthcare Professionals about how to minimise some of the main risks associated with the use of lenalidomide. Please refer also to SmPC (Section 4.2 Posology and method of administration, 4.3 Contraindications, 4.4 Special warnings and precautions for use and 4.8 Undesirable effects).

9.1 Tumour Flare Reaction in Mantle Cell Lymphoma and Follicular Lymphoma Patients

Tumour Flare Reaction (TFR) has commonly been observed in patients with mantle cell lymphoma who were treated with Lenalidomide and very commonly observed in patients with follicular lymphoma treated with Lenalidomide and Rituximab. The patients at risk of TFR are those with high tumour burden prior to treatment. Caution should be practised when introducing these patients to Lenalidomide. These patients should be monitored closely, especially during the first cycle or dose-escalation and appropriate precautions taken.

At the prescriber's discretion, Lenalidomide may be continued in patients with Grade 1 or 2 TFR without interruption or modification. At the prescriber's discretion, therapy with nonsteroidal anti-inflammatory drugs (NSAIDs), limited duration corticosteroids, and/or narcotic analgesics may be administered. In patients with Grade 3 or 4 TFR, withhold treatment with Lenalidomide and initiate therapy with NSAIDs, corticosteroids and/or narcotic analgesics. When TFR resolves to $\leq$ -Grade 1, restart Lenalidomide treatment at the same dose level for the rest of the cycle. Patients may be treated for management of symptoms per the guidance for treatment of Grade-1 and 2 TFR.

9.2 Second Primary Malignancies

The risk of occurrence of Second Primary Malignancies (SPM) must be taken into account before initiating treatment with Lenalidomide either in combination with melphalan or immediately following high-dose melphalan and autologous stem-cell transplantation (ASCT). Prescribers should carefully evaluate patients before and during treatment using standard cancer screening for occurrence of SPM and institute treatment as indicated.

An increase of SPM has been observed in clinical trials in previously treated myeloma patients with Lenalidomide/Dexamethasone compared to controls, mainly comprising of basal cell or squamous cell skin cancers.

A 2.12-fold increase in incidence rate of solid tumour SPM has been observed in patients receiving Lenalidomide (9 cycles) in combination with Melphalan and Prednisone (1.57 per 100 person- years) compared with melphalan in combination with Prednisone (0.74 per 100 person-years). Cases of haematological SPM such as acute myeloid leukaemia (AML) have been observed in clinical trials of newly diagnosed multiple myeloma in patients taking Lenalidomide in combination with Melphalan or immediately following high dose Melphalan and ASCT (HDM/ ASCT; see Section 4.4 of the SmPC). This increase in risk of haematological SPM was not observed in clinical trials of newly diagnosed multiple myeloma in patients taking Lenalidomide in combination with Dexamethasone compared to Thalidomide in combination with Melphalan and Prednisone. Please refer to the label for further details.

9.3 Progression to Acute Myeloid Leukaemia in Low- and Int-1-Risk MDS Patients

Baseline variables including complex cytogenetics and TP53 mutation are associated with progression to AML in subjects who are transfusion dependent and have a deletion (5q) abnormality. As a consequence, the benefit/ risk balance of lenalidomide when MDS is associated with Del (5q) and complex cytogenetics is unknown (see Section 4.4 of the SmPC).

9.4 Blood Donation

All patients should not donate blood during treatment (including dose interruptions) and for at least 4 weeks after cessation of treatment with Lenalidomide S.K..

10. Special precautions for disposal and other handling

Capsules should not be opened or crushed. If powder from pomalidomide makes contact with the skin, the skin should be washed immediately and thoroughly with soap and water. If pomalidomide makes contact with the mucous membranes, they should be thoroughly flushed with water.

Healthcare professionals and caregivers should wear disposable gloves when handling the blister or capsule. Gloves should then be removed carefully to prevent skin exposure, placed in a sealable plastic polyethylene bag 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.

Any unused medicinal product or waste material should be disposed of in accordance with local requirements. Unused medicinal product should be returned to the pharmacist at the end of treatment.

For full details, please refer to the SmPC.

When Lenalidomide S.K. is given in combination with other medicinal products, the corresponding SmPC must be consulted prior to treatment.

a. Description of the Pregnancy Prevention Programme and Patient Categorisation Algorithm

Evaluate new patient

Male

Female

Non-childbearing potential

With childbearing potential*

Start Lenalidomide S.K..

Condom required for sexual intercourse (even if vasectomised) for the duration of Lenalidomide S.K. treatment, during dose interruptions, and for at least 4 weeks 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 $\geq$ 50 years and naturally amenorrhoeic for $\geq$ 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.

If not already using effective contraception, start at least 2 effective contraception at least 4 weeks prior to initiation of therapy unless practicing absolute and continued abstinence:

- Contraception includes highly effective methods: either implant, levonorgestrel releasing intrauterine system, medroxyprogesterone acetate depot, tubal sterilisation, vasectomised partner, ovulation inhibitory progesterone-only pill (i.e. desogestrel) AND additional effective barrier method (condom, diaphragm, cervical cap)
- Contraception continues during treatment, including dose interruptions, and for at least 4 weeks after treatment discontinuation.

* 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 S.K. treatment

Test for pregnancy (minimum sensitivity of 25mIU/ml) after at least 4 weeks of adequate contraception (even if sexually abstinent)

Negative

Positive

Start Lenalidomide S.K. 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 S.K. Treatment

b. Check List for Physicians

Items to discuss	I have explained this to my patient [YES/NO]
Is Lenalidomide S.K. prescribed to the patient in line with its approved indication?	
The patient was explained that Lenalidomide S.K. is a derivative of Thalidomide known to cause severe birth defects and that they must not get pregnant whilst taking it.	
The patient was explained that: For male patients: • Patient must use condoms during Lenalidomide S.K. therapy and 4 weeks after stopping therapy. • Male patients should not donate semen or sperm during treatment (including during dose interruptions) and for at least 4 weeks following discontinuation of Lenalidomide. For female patients: If she is a women of childbearing potential, she must consistently and correctly use 2 contraception methods before and during treatment (unless absolute and continuous sexual abstinence confirmed on monthly basis). The methods must include a highly effective method (i.e. an intra-uterine device or implant) and additional effective barrier methods (i.e. condom, Diaphragm, cervical cap).	
The patient was explained that the risk persists even after the medication is stopped and that she/ or the male patient partner must not get pregnant within: <u>4 weeks after stopping treatment.</u>	
The patient has received advice on contraception which is appropriate for him/her and has committed to using it throughout the risk period.	
The patient is aware of the risk of contraceptive failure.	
For Women of Childbearing Potential: Once established on contraception for 4 weeks the patient is required to have a medically supervised negative pregnancy test. The first prescription for Lenalidomide S.K. can only be given after one negative medically supervised pregnancy test. This includes those women of childbearing potential who confirm absolute and continued abstinence. This is to make sure she is not already pregnant before starting treatment.	

Items to discuss	I have explained this to my patient [YES/NO]
For Women of Childbearing Potential: Patient was explained that in order to support regular follow up, including pregnancy testing and monitoring, the prescription should be limited to 4 weeks.	
For Women of Childbearing Potential: Patient was explained that Lenalidomide S.K. prescription should be signed no later than 3 days from the negative pregnancy test Dispensing of Lenalidomide S.K. to women of childbearing potential should occur within 7 days of the prescription.	
For Women of Childbearing Potential: Patient was explained the need for and agrees to pregnancy testing before, during and after treatment.	
For Women of Childbearing Potential: Patient was explained the need for periodic pregnancy tests with 28 days intervals throughout treatment and also for a period of 4 weeks after stopping treatment.	
The patient has received a copy of the educational package.	
The patient was explained that, according to Israeli ministry of health requirements, Lenalidomide S.K. is under controlled distribution program and that information regarding all patients and prescriptions is collected by S.K. Pharma. The information might be shared with the ministry of health and other applicable bodies, per regulatory requirements.	
The patient was explained that the maximum duration of a prescription for women of childbearing potential can be for a maximum duration of treatment of 4 weeks, and prescriptions for all other patients can be for a maximum duration of treatment of 12 weeks.	
The female patient knows to contact the physician if they have unprotected sex, miss their period, become pregnant, or suspect that they have become pregnant during the risk period.	
If pregnancy occurs, treatment must be stopped, and the patient should be referred to an expert physician specialized or experienced in teratology for advice.	
Patient was explained that Lenalidomide S.K. has been prescribed to him/her only and must not be shared with others and that they should always return any unused capsules to the pharmacist for safe disposal as soon as possible	
Patient was explained that they must not donate blood during treatment with Lenalidomide S.K. (including dose interruptions) and for 4 weeks after discontinuation.	

c. Reports on Pregnancy during Treatment with Lenalidomide S.K. should be sent to the following Parties:

To the Ministry of Health:

By the portal of side effects reporting at the homepage of the Ministry of Health website www.health.gov.il or by entering the link:
<https://sideeffects.health.gov.il/>

To K.S. Kim International (S.K. Pharma)Ltd.:

Adverse events:

Email: report@sk-pharma.com

Phone: 03-6114543

Fax: 077-3181051

Program registration forms should be sent to:

Email: lenalidomide@sk-pharma.com

Fax: 077-3181051

Phone: 03-6114543

The above contacts can be also used for reporting adverse events during the treatment with Lenalidomide S.K.

This brochure and its content were reviewed and approved by the Ministry of Health in ~~May 2025~~

d. Information for physicians, the healthcare professionals, patients and pharmacists about the use of personal information - risk management program relating to the administration of S.K. IMiDs¹ drugs.

S.K. PHARMA Pharmaceutical Industries Ltd. (hereinafter: “S.K. Pharma” 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 is collected through the completion of a paper or online registration form for the risk management program (the form is completed by the patient, the treating physician or the pharmacist), which includes, inter alia, name, 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, language preferences, details about parents and/or guardians and/or participation in instructional sessions. The personal information that we collect from physicians, the treatment staff and/or from pharmacists through their completion of the program registration form includes name, institutional affiliation, occupation, license number, telephone number and e-mail address. We also collect any additional personal information that will be provided by patients, physicians, treatment staff and pharmacists in the future within the framework of the risk management plan. We also collect any additional personal information that you provide to us now or in the future. 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 and accepted information-security 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 purposes for collecting and saving the information about you are for the

¹ Immunomodulatory imide Drugs (IMiDs) by S.K. Pharma (Lenalidomide S.K. / Pomalidomide S.K.)

purposes for collecting and saving the information about you are for the participation in risk management programs as is required by law and regulation, for the operation of this program and for the controlled dispensing of the medicine within its framework. We will share the information with the authorized authorities for the purpose of complying with these requirements.

We use external companies as our subcontractors 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, which will be operated on our behalf.

All of the subcontractors that will operate on our behalf will be subject to obligations regarding the use of information and to the obligations by law. 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 but, in such instance, the recipients of the information will undertake to safeguard confidentiality and to act in compliance with the relevant provisions specified in this document.

Right to peruse and amend

You have a right to demand to peruse your information or to update or correct it in particular instances. 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 agree that my personal information will be shared and processed as described above and in the respected registration forms. I understand that I am under no legal obligation to provide this information, but without it, I will not be able to receive S.K. Pharma's IMiDs drugs.

www.sk-pharma.com
For further information, read the entire SmPC carefully before using the medicine.

Program registration forms should be sent to:

Email: lenalidomide@sk-pharma.com

Fax: 077-3181051

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