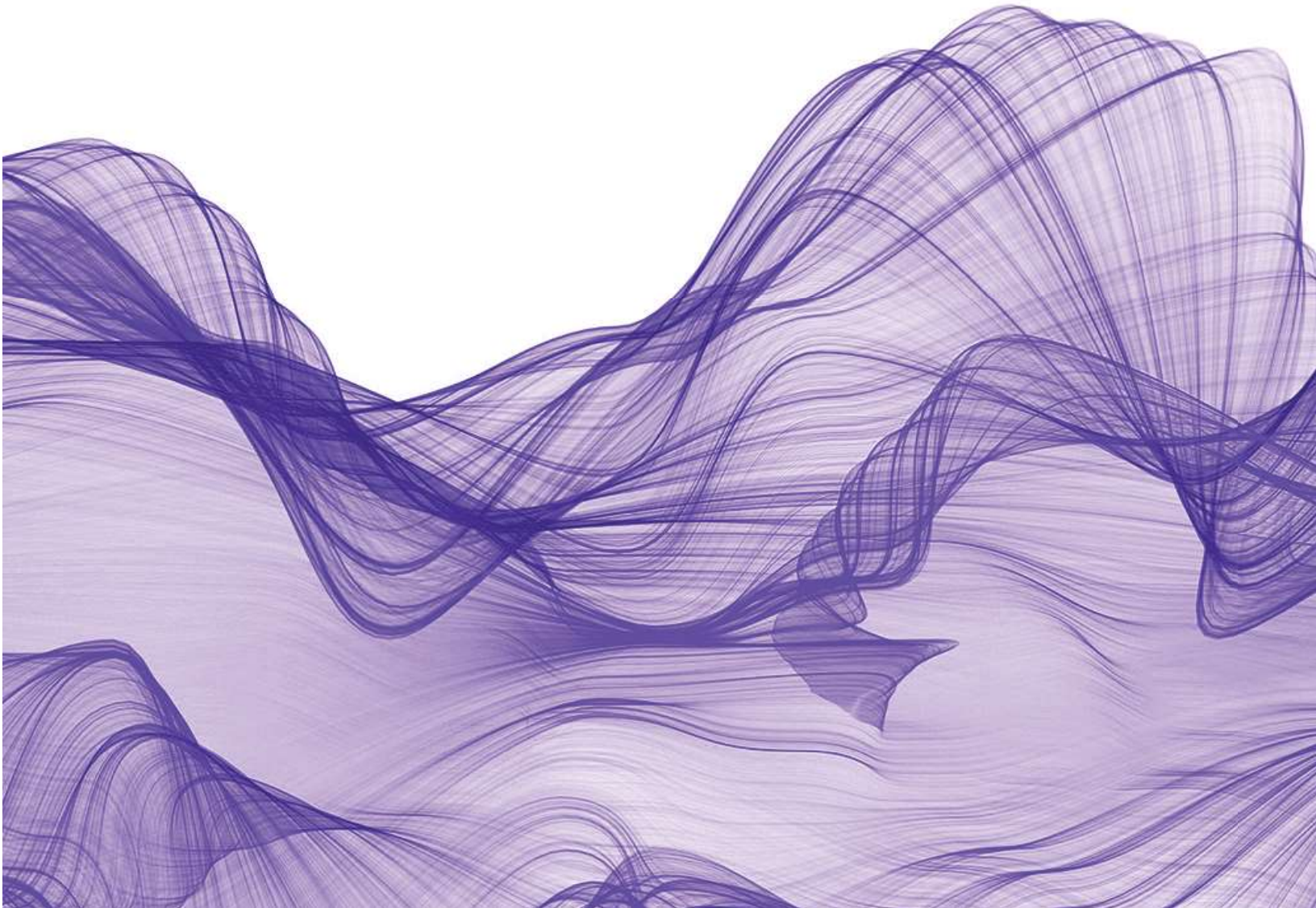
K.S. KIM INTERNATIONAL

Lenalidomide S.K. (Lenalidomide)

RMP- Risk Management Plan

PPP- Pregnancy Prevention Program



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1. General Information

The program is intended for the product Lenalidomide S.K. (Lenalidomide).

K.S. Kim International Ltd. (K.S. Kim) is the License holder and importer for the product in Israel.

RMP version v.1

Submission date: November 2020

1.1. Product Description & Mechanism:

Lenalidomide S.K. belongs to the Pharmacotherapeutic group of "Other immunosuppressants." (ATC code: L04AX04).

The Lenalidomide S.K. mechanism of action includes anti-neoplastic, anti-angiogenic, proerythropoietic, and immunomodulatory properties.

1.2. Indications

Lenalidomide S.K. is indicated for:

a) Multiple Myeloma

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.

b) Myelodysplastic Syndromes

Lenalidomide S.K. is indicated for 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.

c) Mantle Cell Lymphoma

Lenalidomide S.K. is indicated for the treatment of adult patients with relapsed and/or refractory mantle cell lymphoma (MCL).

1.3. Dosages Registered in Israel

Lenalidomide S.K. is available in Israel with the following dosages:

I. 2.5mg
II. 5mg
III. 7.5mg
IV. 10mg
V. 15mg
VI. 20mg
VII. 25mg

1.4. List of "Important Risks" and "Missing Information"

"Important risks" of Lenalidomide S.K. are risks that need special risk management activities to further investigate or minimize the risk so that the medicinal product can be safely administered.

"Important risks" can be regarded as "identified" or "potential". "Identified risks" are concerns for which there is sufficient proof of a link with the use of Lenalidomide S.K. "Potential risks" are concerns for which an association with the use of this medicine is possible based on available data, but this association has not been established yet and needs further evaluation.

"Missing information" refers to information on the safety of the medicinal product that is currently missing and needs to be collected (e.g. on the long-term use of the medicine).

"Important" "identified" and "potential" risks are summarized in **Table 1.**

Table 1: List of Important Risks and Missing Information

Important Identified Risks	– Teratogenicity – Serious Infection due to Neutropenia – SPM (second primary malignancy) Important Identified Risk Related to Indication/Target Population – For MCL: TFR (Mantle Cell Lymphoma: Tumour Flare Reaction)
Important Potential Risks	– Cardiac failure – Cardiac arrhythmias – Ischemic Heart Disease (including Myocardial Infarction) – Off-label use
Missing Information	None

1.5. Summary of Important Risks

The important risks are summarized in **Table 2** to **Table 8**.

Table 2: Important Identified Risk: Teratogenicity	
Evidence for linking the risk to the medicine	Lenalidomide S.K. is structurally related to thalidomide, which is known to cause serious birth defects and death of the foetus. In nonclinical studies, Lenalidomide induced malformations similar to those described with thalidomide. Therefore, a teratogenic effect of Lenalidomide S.K. is expected, and Lenalidomide S.K. is contraindicated during pregnancy.
Risk factors and risk groups	The 'at risk' group comprises FCBP (Female of Childbearing Potential) or female partners of male patients treated with Lenalidomide S.K., and there are no risk factors.
Risk minimization measures	**Routine risk minimization activities**: Section 4.1 of SmPC: contraindicated in pregnant women and in FCBP unless all the conditions of the K.S. Kim PPP are met. Section 5 of SmPC: warnings and precautions for use – Criteria for women of non-childbearing potential – Counselling – Contraception – Pregnancy testing – Precautions for men – Additional precautions – Reference to educational materials, prescribing and dispensing restrictions. Section 8.1, 8.2 & 8.3 of SmPC: fertility, pregnancy, and lactation. Sections 4.1, 5.1 & 5.2 of SmPC: the potential teratogenic effects of Lenalidomide S.K. are highlighted. **Pack size:** The pack is based on a maximum 4-week supply of capsules to ensure that FCBP are required to obtain a new monthly prescription with a medically supervised pregnancy test. Legal status: Lenalidomide S.K. is subject to restricted medical prescription. **Additional risk minimization measures** o K.S. Kim PPP o Educational material for HCP o Educational material for patient o Patient information booklet which includes checklists. o Advice in SmPC, o System to ensure appropriate measures have been completed.

Table 3: Important Identified Risk: Serious Infection due to Neutropenia	
Evidence for linking the risk to the medicine	In clinical trials, neutropenia has been reported as a consequence of Lenalidomide S.K. treatment; ≥ Grade 3 and ≥ Grade 4 infections have occurred in the context of neutropenia (any grade).
Risk factors and risk groups	The combination of Lenalidomide S.K. with melphalan and prednisone in clinical trials of newly diagnosed multiple myeloma (NDMM) patients is associated with a higher incidence of Grade 4 neutropenia than MPp+p (melphalan, prednisone and placebo followed by placebo) treated patients (SmPC, Section 5.3). The proportion of patients who experienced Grade 3 or 4 myelosuppression in one study of Lenalidomide S.K.-treated patients with multiple myeloma (MM) was significantly higher for patients who had prior high-dose chemotherapy and stem cell transplantation, compared with those that did not (Richardson, 2006b). Impairment of antibody response, neutropenia, treatment with glucocorticoids, and reduction of normal Ig all increase the likelihood of infection. While a much greater proportion of Lenalidomide S.K./dexamethasone patients experienced neutropenia relative to placebo/dexamethasone patients, this increased risk did not translate into an infection risk of the same magnitude in either the total study population or in the study population restricted to Grade 3 or 4 toxicities. Lenalidomide S.K. treatment in Myelodysplastic syndromes (MDS) patients is associated with a higher incidence of Grade 3 or 4 neutropenia compared with patients on placebo (SmPC, Section 5.3). In patients with MDS, those experiencing neutropenia while receiving Lenalidomide S.K. may be at increased risk for infections.
Risk minimization measures	**Routine risk minimization activities**: ○ Section 2.1 of SmPC: dose reduction advice for neutropenia. ○ Section 5.3 of SmPC: warning of neutropenia, and infection with or without neutropenia, and advice for monitoring patients, including blood testing for neutropenia. Advice that patients should report febrile episodes promptly. Advice regarding establishing Hepatitis B (HBV) status before treatment, use in patients previously infected with HBV and monitoring for signs and symptoms of active HBV infection throughout therapy. ○ Listed as ADRs in Section 6 of SmPC. ○ Advice to patients in PIL, including that the doctor is advised to check if the patient has ever had HBV infection prior to starting Lenalidomide S.K. treatment. **Additional risk minimization measures:** ○ None.

Table 4: Important Identified Risk: SPM	
Evidence for linking the risk to the medicine	In clinical trials, Acute Myeloid Leukaemia (AML) and B-cell malignancies have been reported in patients treated with Lenalidomide S.K. Based on clinical trial data, Lenalidomide S.K. may increase the risk of Non-melanoma skin cancer (NMSC). Patients with MM also have an increased risk of NMSC. Patients treated with Lenalidomide S.K. may be at increased risk of developing new cancers. The reason for this is not clear, but further investigations are being undertaken.
Risk minimization measures	**Routine risk minimization activities**: o Section 5.2 of SmPC warning of secondary primary malignancies (SPM) and advice for cancer screening. o Listed as ADRs in Section 6.1 of SmPC. o Advice to patients provided in PIL.

<u>Table 5:</u> Important Identified Risk: Tumour Flare Reaction (MCL Indication)	
Evidence for linking the risk to the medicine	Based on clinical trial data, Lenalidomide S.K. may increase the risk of Tumour flare reaction (TFR) in patients with MCL.
Risk factors and risk groups	TFR has been associated with greater tumour burden in Chronic lymphocytic leukaemia (CLL) (Ferrajoli, 2008). In Study MCL-002, in the final multivariate model, high MIPI (MCL International Prognostic Index) score at diagnosis (p=0.084) and bulky disease at baseline (p=0.020) appeared to be strong and independent risk factors for TFR.
Risk minimization measures	**Routine risk minimization activities**: o Section 2.4 of SmPC: dose interruption advice for TFR. o Section 5.3 of SmPC warning. o Listed as an ADR in Section 6.1 of SmPC.

Table 6: Important Potential Risk: Cardiac Failure and Cardiac Arrhythmias (Part 1/2)	
Evidence for linking the risk to the medicine	Based on clinical trial data, a higher incidence of cardiac failure has been observed; the reason for this is not clear. Based on clinical trial data, a higher incidence of cardiac arrhythmia was observed in the Lenalidomide S.K. arm.
Risk factors and risk groups	No particular risk groups or risk factors have been identified for Lenalidomide S.K. In MM and MDS no differences in frequency, severity, serious outcomes, and apparent risk level of cardiac failure AEs have been observed. Cardiac symptoms in patients with MDS are often due to anaemia and may be due to iron overload and side effects of therapy (Mateen, 2006). In a study of 840 MDS patients, Della Porta (2007) reported that heart failure (28% vs 18%, p = 0.001) and cardiac death (69% vs 55%, p = 0.03) were significantly more frequent in transfusion-dependent patients. In a Cox analysis with time-dependent covariates, transfusion-dependent patients showed an increased risk of non-leukemic death (HR = 2.12; p ≤ 0.001), heart failure (HR = 1.34; p = 0.03), and cardiac death (HR = 2.99; p = 0.01). The development of secondary iron overload significantly affected the risk of non-leukemic death and OS (Overall survival) (HR = 1.25 and 1.16, respectively; p < 0.001), and this effect was maintained after adjusting for transfusion burden. Iron overload specifically increased the risk of developing heart failure (HR = 1.17, p < 0.001). General risk factors for Chronic Heart Failure (CHF) include increasing age, previous heart disease, diabetes, hypertension, amyloidosis, and previous anthracycline-based chemotherapy treatment (Hershman, 2008). Standard risk factors for atrial fibrillation include advancing age, European ancestry, body size (greater height and body mass index), electrocardiography features (left ventricular hypertrophy, left atrial enlargement), diabetes, systolic blood pressure and presence of cardiovascular disease (ie, CHD, heart failure, valvular heart disease). Other factors include clinical and subclinical hyperthyroidism, chronic kidney disease, and heavy alcohol consumption. Familial aggregation studies have identified a role for genetic factors, although such factors probably account for a small proportion of cases (Go, 2014). In a case-control study of 385 eligible cases of new-onset atrial fibrillation embedded within the Rotterdam study, the risk of new-onset atrial fibrillation was significantly higher for persons who received a corticosteroid prescription within 1 month before the atrial fibrillation index date (van der Hooft, 2006).

Table 6: Important Potential Risk: Cardiac Failure and Cardiac Arrhythmias (Continued) (Part 2/2)	
Risk factors and risk groups (Continued)	Only high-dose corticosteroid use was associated with increased risk (OR = 6.07; 95% CI: 3.90-9.42). The association of atrial fibrillation was independent of indication for use. Risks were increased not only in patients with asthma or chronic obstructive pulmonary disease, but also in patients with rheumatic, allergic, or malignant haematologic diseases.
Risk minimization measures	**Routine risk minimization activities**: – Listed as ADRs in Section 6.1 of SmPC. – Listed in PIL. **Additional risk minimization measures:** None.

Table 7: Important Potential Risk: Ischaemic Heart Disease (Including Myocardial Infarction)	
Evidence for linking the risk to the medicine	In clinical trials, ischaemic heart disease has been reported in patients treated with Lenalidomide S.K. Myocardial infarction occurs relatively often in individuals of the older age groups that most often develop the target indications of MM, MDS and MCL.
Risk factors and risk groups	Risk factors for 10-year coronary risk based upon the Framingham Heart Study include elevated blood pressure, elevated cholesterol, high-density lipoprotein- C, presence of diabetes and cigarette smoking (Go, 2014). These factors are in addition to the well-known relationships between coronary risk and age and gender. In Europe, smoking remains a major public health issue and about 20% of death from CVD in men and about 3% of deaths from CVD in women are due to smoking. Levels of obesity are high across Europe in both adults and children, although rates vary substantially between countries. Participation in physical activity is low. Increases in population body mass index over the interval 1980 to 2008 were noted in almost all countries. The prevalence of diabetes in Europe is high and has increased rapidly over the last ten years, increasing by more than 50% in many countries (Nichols, 2012).
Risk minimization measures	**Routine risk minimization activities**: The association between ischaemic heart disease and Lenalidomide S.K. is unknown. Close monitoring will continue. – Myocardial infarction is included in Sections 5.3 and 6.1 of the SmPC. **Additional risk minimization measures:** None.

Table 8: Important Potential Risk: Off-label Use	
Evidence for linking the risk to the medicine	There is potential for the use of Lenalidomide S.K. in indications other than the approved indications.
Risk factors and risk groups	Not applicable
Risk minimization measures	**Routine risk minimization activities**: – Collection of off-label use data in accordance with pharmacovigilance requirements in Israel. **Additional risk minimization measures:** None.

2. Pregnancy Prevention Program (PPP)–

2.1. Education, Therapy management, Distribution Control

Lenalidomide S.K. is structurally related to thalidomide, a known human teratogenic substance that causes severe life-threatening birth defects. Lenalidomide S.K. induced, in monkeys, malformations similar to those described with thalidomide. If Lenalidomide S.K. is taken during pregnancy, a teratogenic effect of Lenalidomide S.K. in humans is expected.

Lenalidomide S.K. is therefore contraindicated during pregnancy and in women of childbearing potential unless the conditions of the Pregnancy Prevention Program described in this pack are carried out.

It is a requirement of the Pregnancy Prevention Program that all healthcare professionals ensure that they have read and understood this pack before prescribing or dispensing Lenalidomide S.K. for **all** patients.

The following are the **core requirements** of the Pregnancy Prevention Program

- All healthcare professionals dispensing or prescribing Lenalidomide S.K. must read the Lenalidomide S.K. "Healthcare Professional's Information Booklet."
- All Doctors who prescribe Lenalidomide S.K. must agree to implement risk minimisation by registering with K.S. Kim using the "Doctor Registration Form."
- For all pharmacies which dispense Lenalidomide S.K., the responsible pharmacist must register the pharmacy and must agree to implement risk minimisation by registering with K.S. Kim using the "Pharmacy Registration Form." In the event that the Responsible Pharmacist changes for the institution, the Responsible Pharmacist, is obliged to inform K.S. Kim of this change by re-registering using the Pharmacy Registration form.
- All prescriptions for Lenalidomide S.K., must be sent to K.S. Kim for authorisation. All prescriptions for Lenalidomide S.K. must be accompanied by a Lenalidomide S.K. Prescription Authorisation via "Monthly Pregnancy Test Form", unless the patient is exempt which must be stated in "Patient Registration Form."

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. The prescriber should provide comprehensive advice and counselling to all patients.

The prescriber must ensure that for women of childbearing potential (both patients and patients' partners):

- The patient complies with the conditions of the Pregnancy Prevention Program, including

    a. Confirmation that they have an adequate level of understanding
    b. The patient has acknowledged the aforementioned conditions.
    c. The prescriber must provide patients with the "Patient Information Booklet."
    d. Maximum duration of a prescription is 4 weeks.

2.2. Patient and healthcare professional education

All patients must sign an informed consent form confirming their awareness of the risks of treatment, particularly of the risks associated with foetal exposure and their agreement to adhere to the requirements of the program. "Patient Registration Form."

All patients should be given a copy of the "Patient Information Booklet" to take home.

The "Patient Information Booklet" has separate sections containing information for women of childbearing potential, women of non-childbearing potential and men, as well as a section describing safety information relevant to all patients.

All healthcare professionals involved in the prescribing or dispensing of Lenalidomide S.K. must confirm that they have read "Healthcare Professional's Information Booklet" as well as all the "Patient information Booklet". To confirm this, the prescribing doctor must complete and sign "Doctor Registration form" and the Responsible Pharmacist must complete sign the "Pharmacy Registration Form"

2.3. Therapeutic management advice to avoid foetal exposure

For Male Patients

For male patients taking Lenalidomide S.K., pharmacokinetic data has demonstrated that Lenalidomide S.K.is present in human semen. As a precaution and taking into account special populations with prolonged elimination time such as renal impairment, all male patients taking Lenalidomide S.K. must meet the following conditions:

- The expected teratogenic risk if engaged in sexual activity with a pregnant woman or a woman of childbearing potential, was explained

- 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 patient has had a vasectomy**), during treatment and for 4 weeks after dose interruptions and/or cessation of treatment, was explained

  It has been explained to the patient that if his female partner becomes pregnant whilst he is taking Lenalidomide S.K. or shortly after he has stopped taking Lenalidomide S.K., he should inform his treating physician immediately and that it is recommended to refer the female partner to a physician specialised or experienced in teratology for evaluation and advice.

Women of non-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 amenorrhoeic for ≥ 24 months.
  - Please note amenorrhea following cancer therapy or during lactation 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.

Treating physicians 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, Lenalidomide S.K.is contraindicated unless all the following are met:

- The expected teratogenic risk to the unborn child was explained
- 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, was explained
- 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

    • She has been informed and understands the potential consequences of pregnancy and the need to rapidly consult if there is a risk of pregnancy

    • She has been informed about the need to commence the treatment as soon as Lenalidomide S.K. is dispensed following a negative pregnancy test

    • She has been informed about the need and accepts to undergo pregnancy testing every 4 weeks

    • She acknowledges that she has been explained the hazards and necessary precautions associated with the use of Lenalidomide S.K.

    • If she becomes pregnant whilst taking Lenalidomide S.K., she should stop therapy and inform her treating physician immediately. It is recommended to refer the partner to a physician specialised or experienced in teratology for evaluation and advice.

2.4. Contraception

Women of childbearing potential must use one effective method of contraception for 4 weeks before therapy, during therapy, and until 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. If not established on effective contraception, the patient must be referred to an appropriately trained health care professional for contraceptive advice in order that contraception can be initiated.

The following can be considered to be examples of suitable methods of contraception:

- 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)

Combined oral Contraceptive Pills

Because of the increased risk of venous thromboembolism in patients with multiple myeloma taking Lenalidomide S.K. in combination therapy, and to a lesser extent in patients with multiple myeloma, myelodysplastic syndromes and mantle cell lymphoma taking Lenalidomide S.K. monotherapy, combined oral contraceptive pills are not recommended.

If a patient is currently using combined oral contraception the patient should switch to one of the 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 co-treatment with dexamethasone.

Implants & IUDs

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.

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.

2.5. Pregnancy testing

According to local practice, medically supervised pregnancy tests with a minimum sensitivity of 25 mIU/mL must be performed for women of childbearing potential as outlined below. This requirement includes women of childbearing potential who practice absolute and continuous abstinence. Ideally, pregnancy testing, issuing a prescription and dispensing should occur on the same day, but it can be prescribed within 3 days. Dispensing of Lenalidomide S.K.to women of childbearing potential should occur within 7 days of the prescription.

2.6. Prior to starting treatment

Pregnancy tests should be performed on the day of the prescribing visit or in the 3 days prior to the visit to the prescriber; once the patient had been using effective contraception for at least 4 weeks. This test should ensure the patient is not pregnant when she starts treatment with Lenalidomide S.K.
The results **must** be included in **"Patient Registration form"** and this can also be included in the "Monthly Pregnancy Test Form" **and** sent to K.S. Kim.

2.7. 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. This should be included in the "Monthly Pregnancy Test Form" **and** sent to K.S. Kim.

2.8. Requirements in the event of pregnancy

Upon suspicion of pregnancy during Lenalidomide S.K. therapy (or within 4 weeks from stopping treatment), the doctor should inform K.S. Kim immediately.

A pregnancy report (while on Lenalidomide S.K. therapy) should be provided by filling-in "Pregnancy Report."

2.9. Educational materials, prescribing and dispensing restrictions

In order to assist patients in avoiding foetal exposure to Lenalidomide S.K., the marketing authorisation holder will provide educational material to healthcare professionals and patients 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 doctor must inform all patients about the expected teratogenic risk and the strict pregnancy prevention measures as specified in the Pregnancy Prevention Program and provide patients with appropriate patient information booklet. A national controlled distribution system has been implemented in collaboration with the Ministry of Health.

- Healthcare Professional's Information Booklet
- Patient Information Booklet
- Doctor Registration Form
- Pharmacy Registration Form
- Patient Registration Form
- Monthly Pregnancy Test Form
- Pregnancy Report

2.10. Controlled distribution

In order to facilitate the controlled distribution of the product Lenalidomide S.K. A legally authorised patients' data base will be kept at K.S. Kim. All the following signed declaration will be kept at K.S. Kim, in accordance with the legal demands of managing patient's data base.

Before entering the details of patients and healthcare professionals to the database, their signed consent forms will be obtained.

Before registration all Healthcare professionals must read, agree and understand their responsibilities in regards to the **seven** information documents and forms mentioned above.

Before registration, all patients must receive the "Patient Information Booklet" and be counselled about the risk management plan.

Registration form for the doctor to enter the Risk Management Program, and that they confirm to the storage of their personal information by K.S. Kim. will be signed and sent to K.S Kim (Doctor Registration Form).

Registration form for the pharmacy and it's responsible pharmacist, and the confirmation to the storage of their personal information by K.S. Kim., including the pharmacists license number and contact details, stating for the pharmacy that for women of child bearing potential, a monthly approval for dispensing of Lenalidomide S.K. will only be performed with a Doctor's approved negative pregnancy test results. (Pharmacy Registration Form)

Registration form for patients stating that they received and understood the information regarding the risk and mitigation steps, and that they confirm to the storage of their personal information by K.S. Kim. (Patient Registration Form)

The product “Lenalidomide S.K.” will be sent to the pharmacy from K.S. Kim’s distributer “Novolog”, **only** after all of the declarations from the Pharmacy, Doctor and patient are signed and entered into K.S. Kim database.

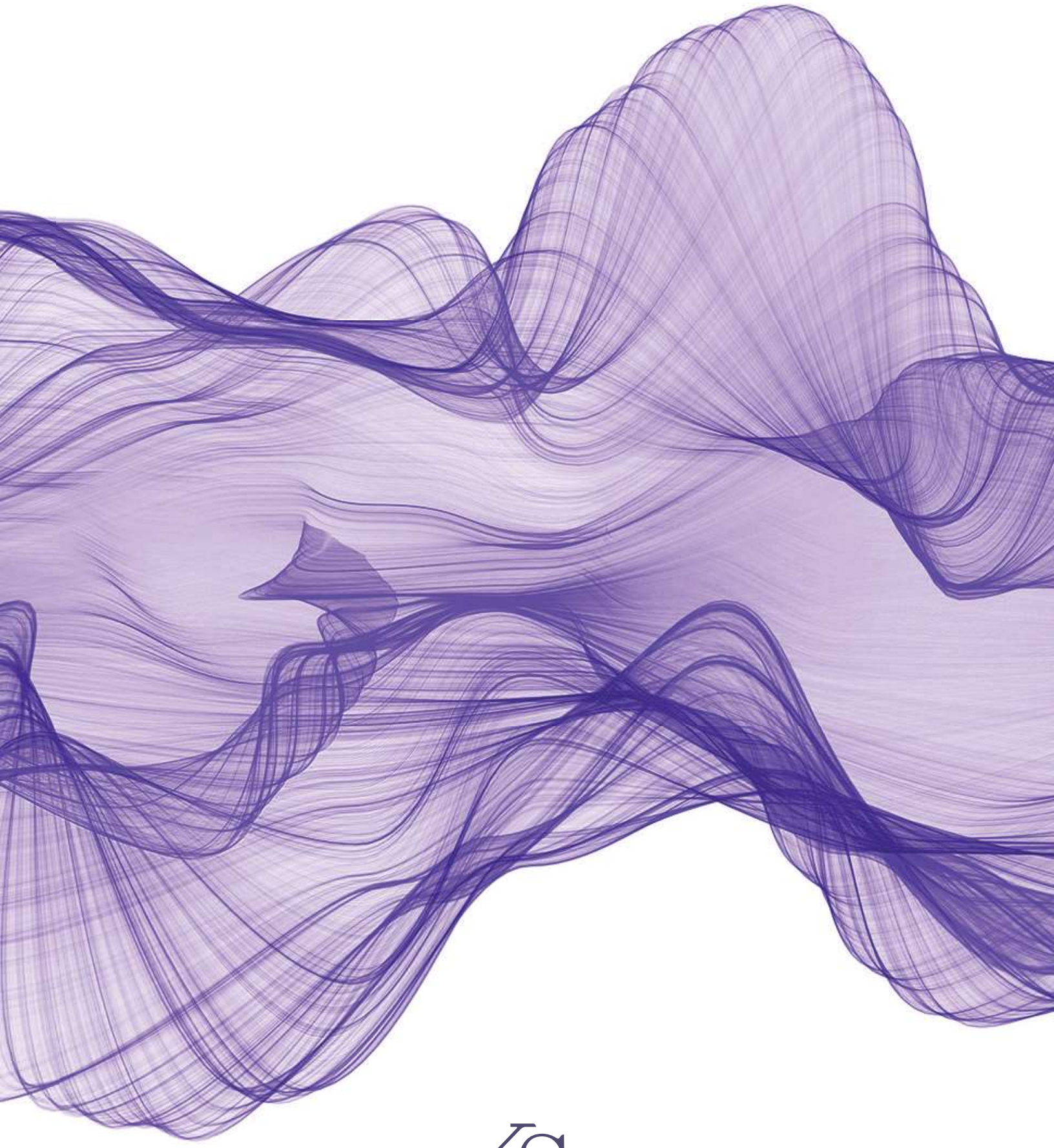
For female patient of childbearing potential, a negative pregnancy result will also be required.

Pregnancy test prior to initiating treatment should be performed on the day of the prescribing visit or in the 3 days before the visit to the prescriber; once the patient had been using effective contraception for at least 4 weeks.

The pregnancy test should be performed **within 3 days** prior to prescribing Lenalidomide S.K. Dispensing of Lenalidomide S.K. to women of childbearing potential should occur within 7 days of the prescription.

Every dispatch of the medicine from “Novolog” to a Pharmacy, will need the approval of K.S. Kim and after verifying the existence of the above documentations. Including the medically supervised monthly pregnancy test (negative) results form, signed by the prescribing physician. (Monthly Pregnancy Test Form)

If pregnancy occurs during treatment with Lenalidomide S.K., **“**Pregnancy Report” must be completed and returned to K.S. Kim.



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