



POMALIDOMIDE S.K.

**Pomalidomide S.K. Risk Management Program
Patient Information Brochure**



SK-PHARMA



Table of Contents

Chapter 1 – General Information for Patients

1. Pomalidomide SK – General Information

- Guide to the drug Pomalidomide SK
- What is the most important information you should know about Pomalidomide SK?

2. Birth Defects and Pregnancy Prevention

- Pregnancy prevention – for female patients and partners of male patients
- What is Pomalidomide SK, and what is it used for?

3. Side Effects

Chapter 2 – Taking Pomalidomide SK – Guidelines for All Patients

1. Who should not take Pomalidomide SK?

2. During and After Treatment

- General information on the safe and effective use of Pomalidomide SK

Chapter 3 – The Pregnancy Prevention Program (PPP/RMP)

1. Information for Women

- Information for non-fertile women (PBCNF)
- Information for fertile women (PBCF)
 - Methods of pregnancy prevention
 - Pregnancy tests to ensure you are not pregnant

2. Information for Men

Chapter 1: General Information for Patients

The goal of this program is to help your physician inform you of the risks associated with treatment with Pomalidomide S.K. and to ensure that you are aware of the precautions you need to take before, during, and after the treatment.

You must understand and agree to the terms of the program to receive treatment with Pomalidomide SK.

1. Pomalidomide S.K. - General Information:

Your physician has enrolled you in the Risk Management Program / Pregnancy Prevention Program (RMP/PPP). Pomalidomide is structurally similar to Thalidomide, a drug known to cause life-threatening birth defects. If Pomalidomide is taken during pregnancy, it is expected to cause harm to the fetus.

Pomalidomide has caused birth defects in animals, and a similar response is expected in humans.



What is the most important information you should know about Pomalidomide S.K.?

- Pomalidomide S.K. is intended only for patients who understand and agree to follow all program instructions.
 - Pomalidomide S.K. may cause side effects – refer to the patient leaflet for more information.
-

2. Birth Defects and Pregnancy Prevention

Pregnancy prevention – for treated women and partners of treated men:

Before starting treatment and each time you receive a new prescription, you must read the patient leaflet enclosed in the packaging of Pomalidomide S.K., as it may contain new information. The patient leaflet is not a substitute for discussing your medical condition and treatment with your physician.

If you become pregnant while taking Pomalidomide S.K., stop taking the drug immediately and contact your physician. Partners of men taking Pomalidomide S.K. should contact their physician immediately if they become pregnant.

What is Pomalidomide S.K. and what is it used for?

Pomalidomide S.K. is an oral medication used to treat multiple myeloma. For more information, refer to the patient leaflet.



3. Side Effects

Like most medications, Pomalidomide S.K. can cause side effects. Some are more common than others, and some may be more severe than others. Most side effects are temporary and can be prevented or managed. It is important to be aware of the expected side effects and to report any side effects you experience to your physician during treatment with Pomalidomide S.K.

Before starting and during treatment, you will undergo routine blood tests, as the drug may cause a reduction in white blood cells (which help fight infections) and platelets (which help stop bleeding). Your physician will instruct you to take a blood test:

- Before starting treatment
- Once a week during the first 8 weeks of treatment
- At least once a month after that.

Your physician may adjust the dose of Pomalidomide S.K. or decide to stop treatment based on the results of the blood tests. For more information on side effects, refer to the patient leaflet.



Chapter 2: Taking Pomalidomide S.K. – Instructions for All Patients

Consult your physician for more information or clarification regarding terms used in the Risk Management Program / Pregnancy Prevention Program (PPP/RMP).

1. Do not take Pomalidomide S.K. in the following cases:

• For Women:

You must not take Pomalidomide S.K. if you are:

- Pregnant, planning to become pregnant, or become pregnant while taking the medication, as Pomalidomide S.K. can cause birth defects. If you are of childbearing age, do not take this medication without using two reliable contraceptive methods to prevent pregnancy.
- Women of childbearing potential who do not use two effective methods of contraception for at least 4 weeks before starting treatment, during treatment, and for 4 weeks after stopping treatment, and during breaks between doses. Refer to the "Information for Women" section for further details.
- Wait at least 4 weeks after stopping the medication before trying to conceive.



- **For Men:**

Pomalidomide is found in semen, so:

- Do not take this medication if you are a man who does not use a condom during sexual intercourse with a woman of childbearing potential. Men must use a condom during treatment with Pomalidomide S.K. and for 4 weeks after stopping treatment.
- For more information, refer to the "Information for Men" section.

For All Patients:

- Do not take Pomalidomide S.K. if you are allergic to any of its ingredients. The full list of ingredients can be found in the patient leaflet.

2. During and After Treatment:

- Do not share Pomalidomide S.K. with others. This can lead to birth defects or other serious problems.
- Do not donate blood while taking Pomalidomide S.K. and for 4 weeks after stopping treatment.



General Information on the Safe and Effective Use of Pomalidomide S.K.:

Return any unused capsules of Pomalidomide S.K. to the pharmacist or physician. This medication is prescribed to treat your condition. It can be harmful to others, even if their medical condition appears to be similar to yours.

Do not transfer this medication to others!

This brochure summarizes the most important information about pomalidomide S.K. If you are interested in more information, please refer to the leaflet and contact your doctor.

Chapter 3: Pregnancy Prevention Program (PPP/RMP)

To receive treatment, the following conditions must be met:

- The prescribing physician must be registered in the Risk Management Program.
- The pharmacy dispensing the prescription must be registered in the Risk Management Program.
- Your physician must enroll you in the Risk Management Program (after explaining the program to you and obtaining your agreement to its terms).

- o Patients under 18 years of age may only be enrolled with the approval of their guardian.

1. Information for Women


Pomalidomide S.K. can harm an unborn baby:

- Before starting treatment with Pomalidomide S.K., you must discuss your chances of becoming pregnant with your physician.
- Some women who do not have regular menstrual periods or who are nearing menopause can still become pregnant.
- You may need to meet with a gynecologist and undergo tests to confirm that you are not able to become pregnant. Your physician will advise you.
- Women of childbearing potential, even if they do not plan to become pregnant, must follow the precautions outlined in the "Information for Women of Childbearing Potential" section.

1.1 Information for Non-Fertile Women:

Women who cannot conceive are:

- Women aged 50 or older with natural menopause lasting at least 12 consecutive months*
- Women who have undergone bilateral oophorectomy or hysterectomy


- 
- Women with confirmed ovarian failure, as certified by a gynecologist
 - Women with XY genotype, Turner syndrome, or uterine agenesis (underdeveloped uterus)
 - Any other case as determined by the treating physician

*Absence of menstruation due to cancer treatment or breastfeeding does not exclude the possibility of pregnancy.

*Absence of menstruation due to treatment with Pomalidomide S.K. will be considered pregnancy until proven otherwise.

1.2 Information for Women of Childbearing Potential

- Pomalidomide S.K. can harm an unborn baby.
- Do not take Pomalidomide S.K. if you are pregnant, think you are pregnant, or plan to become pregnant.
- All women of childbearing potential, even if they do not plan to become pregnant, must follow the precautions outlined here to avoid pregnancy and confirm that they are not pregnant.
- Some women who do not have regular menstrual periods or are approaching menopause can still become pregnant.
- You must begin treatment with Pomalidomide S.K. as soon as possible after receiving a negative pregnancy test and a prescription.

- 
- If you think you may be pregnant while taking Pomalidomide S.K. or within 4 weeks after stopping treatment, contact your physician immediately.
 - If you become pregnant during treatment with Pomalidomide, stop the treatment and notify your physician immediately.

Contraceptive Measures:

- You must avoid pregnancy starting from 4 weeks before taking Pomalidomide, during treatment, during temporary breaks in treatment, and for 4 weeks after stopping treatment and during breaks between doses.
- You must use two reliable contraceptive methods simultaneously, using different mechanisms (e.g., oral contraceptives or an intrauterine device along with a barrier method such as a condom or diaphragm with spermicide). This should be done **4 weeks before, during, and 4 weeks after stopping treatment**, including during breaks between doses (unless abstinence from sexual activity is the chosen method).



Or

- Alternatively, you can agree to complete abstinence from sexual activity with your partner for at least 4 weeks before starting treatment, during treatment, including during breaks between doses, and for 4 weeks after stopping treatment.


Not all types of contraception are suitable during treatment with Pomalidomide S.K. You must inform your treating physician about the contraceptives you are using during treatment with Pomalidomide S.K.

You and your partner must discuss with your physician which contraceptive methods are appropriate for you. If necessary, the physician may refer you to a specialist for contraceptive counselling.

You must inform your physician of any changes or discontinuation of contraceptive use.

Pregnancy Testing to Ensure You Are Not Pregnant:

- If you are of childbearing potential, you must undergo pregnancy tests under the supervision of your physician:


- 
- o Before starting treatment (a pregnancy test after 4 weeks of contraceptive use)
 - o Every 4 weeks during treatment
 - o During breaks in treatment
 - o 4 weeks after stopping treatment

Before each new prescription, you are required to undergo a pregnancy test and obtain a negative result.

2. Information for Men


Pomalidomide S.K. is found in seminal fluid, and therefore:

- There is a risk of pregnancy when engaging in unprotected sex with a woman of childbearing potential.
- You must use a condom during sexual intercourse with a woman of childbearing potential or a pregnant woman during treatment and for 4 weeks after stopping treatment, even if you have undergone Vasectomy surgery.

- 
- If your partner becomes pregnant while you are taking Pomalidomide S.K. or within 4 weeks after stopping treatment, you must contact your physician immediately, and your partner should seek immediate medical advice.
 - Do not donate blood or sperm during treatment with Pomalidomide S.K., during any breaks in treatment, and for 4 weeks after stopping treatment.

Special Instructions:

- Do not break, open, or chew the capsules. If the powder from a broken Pomalidomide S.K. capsule comes into contact with your skin, wash the skin immediately with soap and water.
- Healthcare providers and family members should wear disposable gloves when handling the blister or capsules. Gloves should be removed carefully to avoid skin exposure, placed in a sealable plastic bag, and disposed of according to instructions. Hands should then be washed thoroughly with soap and water.
- Pregnant women or women who think they may be pregnant should avoid handling the blister or capsules.

- 
- This medication is prescribed for the treatment of your condition. Do not give it to others, as it may harm them, even if their medical condition appears to be similar to yours. Return any unused medication to the pharmacist after completing treatment.

Patients and caregivers must report all pregnancies to the following entities:

- Ministry of Health via the adverse effect reporting portal:
https://www.gov.il/he/service/adverse_effects_reports
- S.K. Pharma Ltd. (Pharmacovigilance Department):
Fax: 03-3181051 / Tel: 03-6114543 / Email: report@sk-pharma.com

This brochure and its contents have been reviewed and approved by the Ministry of Health in October 2024.

Data Protection: S.K. Pharma Ltd., as the marketing authorization holder for Pomalidomide S.K., is responsible for implementing privacy protection laws and information security regulations, ensuring appropriate safeguards for personal information, with strict adherence to transparency, consent, and individual privacy rights.