

Lotus

POMAGEN (pomalidomide)

Patient Brochure



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Pomagen Patient Brochure

You have been given this booklet because your doctor has prescribed Pomagen (pomalidomide) for you and **Pomagen is expected to be harmful to the unborn child.**

Please refer to the following sections of this brochure for important information about how to avoid the risk of foetal exposure for patients receiving Pomagen:

- For women who are able to become pregnant, please refer to sections 1 & 4.
- For women who are NOT able to become pregnant, please refer to sections 2 & 4.
- For men, please refer to sections 3 & 4.

Section 1: For female patients who are able to become pregnant*

It is important that you do NOT become pregnant while taking Pomagen.

To ensure that an unborn baby is not exposed to Pomagen, you must use effective birth control (contraception):

- For at least 4 weeks before starting Pomagen treatment
- While taking Pomagen (including any treatment interruptions)
- During the 4-week period following the conclusion of your Pomagen treatment

Do not take Pomagen if you are pregnant or think you may be pregnant or planning to become pregnant, as Pomagen is expected to be harmful to an unborn child.

Before starting treatment:

- Your doctor will complete a Patient Agreement Form documenting that you have been informed of the requirements for you NOT to become pregnant during treatment with Pomagen and at least 4 weeks after finishing Pomagen.
- You must use at least one method of birth control (contraception)[†] for at least the 4-week period before starting Pomagen, unless you agree you will NOT engage in sexual activity with a male partner.
- You must have one negative medically supervised pregnancy test confirmed by your doctor
 - Either at the time of consultation, or in the 3 days prior to the visit to the doctor.
 - The pregnancy test must be medically supervised and not a pregnancy test from a pharmacy.

*Includes: women who are menstruating, amenorrhoeic due to previous medical treatment or during breastfeeding, <50 years of age and/or peri-menopausal; women who have not been in natural menopause for 12 consecutive months.

[†]Suitable methods of contraception include: 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 contraceptives are not recommended. Please ask your doctor which birth control method you should use.

During treatment (including treatment interruptions):

- You must ensure that you receive your Pomagen within 7 days after being prescribed the medication by your doctor. Otherwise, you will need a new prescription.
- You should start Pomagen treatment as soon as possible after having a negative pregnancy test result.
- To prevent a pregnancy, you must either:
 - Continue to use at least one effective method of birth control (contraception), or
 - Agree you will NOT engage in sexual activity with a male partner.
- You must also undergo regular medically supervised pregnancy tests, regardless whether continuous abstinence from sexual intercourse with a male partner is practised
 - At least every 4 weeks during treatment,
And
 - The pregnancy tests should be performed on the day of the visit to the doctor or in the 3 days prior to the visit.
- You must not breastfeed or donate blood.
- You should never share your Pomagen capsules.

Note: If you miss a period, experience any abnormality in menstrual bleeding, become pregnant, suspect pregnancy or had sexual intercourse without using an effective means of birth control (contraception):

- **Stop taking your Pomagen immediately, tell your doctor straight away and have a pregnancy test.**

For at least 7 days after treatment:

- You must not donate blood.

For at least 4 weeks after treatment:

- You must continue to use at least one effective method of birth control (contraception).
- You must continue the medically supervised pregnancy tests at least every 4 weeks, ensuring that a pregnancy test is conducted at least 4 weeks after stopping treatment.
- You must not breastfeed.

Note: If you miss a period, experience any abnormality in menstrual bleeding, become pregnant, suspect pregnancy or had sexual intercourse without using an effective means of birth control (contraception):

- **Tell your doctor immediately and have a pregnancy test.**

Section 2: For female patients who are NOT able to become pregnant

IMPORTANT TO REMEMBER:

- Pomagen may cause birth defects or death to unborn babies.

Before starting treatment:

Your doctor will complete a Patient Agreement Form documenting that you are not able to become pregnant.

This means that you:

- are at least 50 years old and have been naturally postmenopausal for at least 1 year OR
- have premature ovarian failure confirmed by a specialist gynaecologist OR
- have had your uterus removed (hysterectomy) OR
- have had both fallopian tubes and ovaries removed OR
- have XY genotype, Turner Syndrome or uterine agenesis

During treatment:

- You must not donate blood.
- You should never share your Pomagen capsules.

For at least 7 days after treatment:

- You must not donate blood.

Section 3: For male patients

IMPORTANT TO REMEMBER:

- **Pomagen may cause birth defects or death to unborn babies.**
- **Pomagen passes into human semen. Men taking Pomagen must NOT cause pregnancy during treatment.**

Before starting treatment:

- Your doctor will complete a Patient Agreement Form documenting that you have been informed of the requirements for your female partner NOT to become pregnant during treatment with Pomagen and for at least 7 days after you finish Pomagen.

During treatment (including treatment interruptions):

- You must use a condom EVERY TIME you have sexual intercourse with a woman who either is pregnant or can become pregnant and she does not use effective contraception (even if you have had a successful vasectomy).
- You must tell your doctor immediately if you had sexual intercourse with a woman without using a condom, or if you think for any reason that your partner may be pregnant.
- You must not donate blood or sperm.
- You should never share your Pomagen capsules.

For at least 7 days after stopping treatment:

- You must continue to use a condom EVERY TIME you have sexual intercourse with a woman who either is pregnant or can become pregnant (even if you have had a successful vasectomy).
- You must tell your doctor if you had sexual intercourse with a woman without using a condom, or if you think for any reason that your partner may be pregnant.
- You must not donate blood, semen or sperm.

Note: You must contact your doctor urgently if you suspect that your female partner is pregnant.

Section 4: Information for all patients:

How and when to take Pomagen

- Pomagen must be given to you by healthcare professionals with experience in treating multiple myeloma.
- You should swallow the Pomagen capsules whole, preferably with water.
- Do not break, open or chew the capsules. Pomagen capsules can be taken either with or without food.
- You should take Pomagen at about the same time on the scheduled days.
- Always take Pomagen exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

What to do if you forget to take your Pomagen

If you forget to take Pomagen at your regular time and

- Less than 12 hours have passed: take your capsule immediately.
- More than 12 hours have passed: do not take your capsule. Take your next capsule at the usual time the next day.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

How to handle Pomagen safely

- You should never share Pomagen with anyone else.
- Caregivers should wear disposable gloves when handling the capsules. Female caregivers who are pregnant or suspect they may be pregnant should not handle the blister or capsule.
- All unused Pomagen capsules should be returned to the pharmacist. Do not throw away any medicines via wastewater or household waste. These measures will help protect the environment.
- Keep this medicine out of the sight and reach of children.
- Do not use Pomagen after the expiry date.
- Do not use this medicine if you notice any damage or signs of tampering to the pack.

Other information

- You should not donate blood during treatment and for at least 7 days after treatment finishes.
- The most common, serious side effects of Pomagen include a reduction in the number of blood cells that fight infection and also the blood cells which help the blood to clot. For this reason, your doctor will arrange for you to have blood tests before treatment, weekly for at least the first 8 weeks of treatment and at least every month after that. Pomagen may also cause blood clots in the veins and arteries. Therefore, you must tell your doctor immediately if you experience:
 - Any fever, chills, sore throat, cough, mouth ulcers or any other symptoms of infection.

- Any bleeding or bruising in the absence of an injury.
- Any chest or leg pain.
- Any shortness of breath.

If you have any risk factors for developing thromboembolic events, e.g., smoking, high blood pressure, high cholesterol, a clotting disorder, a previous blood clot (in a vein or artery), you should tell your doctor.

- If you experience any side effects whilst taking Pomagen you should tell your doctor or pharmacist.

Speak with your doctor or pharmacist for more information about Pomagen.

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