Pomolide
pomalidomide

Pomolide™
(pomalidomide)

NEW ZEALAND
PATIENT GUIDE

WARNING: If pomalidomide is taken during pregnancy, it may cause birth defects or death to an unborn baby. Women should be advised to avoid pregnancy whilst taking Pomolide (pomalidomide), during dose interruptions, and for 4 weeks after stopping the medicine.

What is Pomolide™? / Why am I taking Pomolide™?[1]

Pomolide™ contains the active ingredient pomalidomide. Pomalidomide belongs to a group of medicines called immunomodulating agents.

Pomolide™ is used in combination with another medicine called 'dexamethasone' (a steroid medicine) to treat adult patients diagnosed with Multiple Myeloma (MM). It is prescribed for patients whose disease has progressed after two prior therapies.

Pomolide™ is available in the following strengths:
Pomalidomide 1 mg, 2 mg, 3 mg, 4 mg.

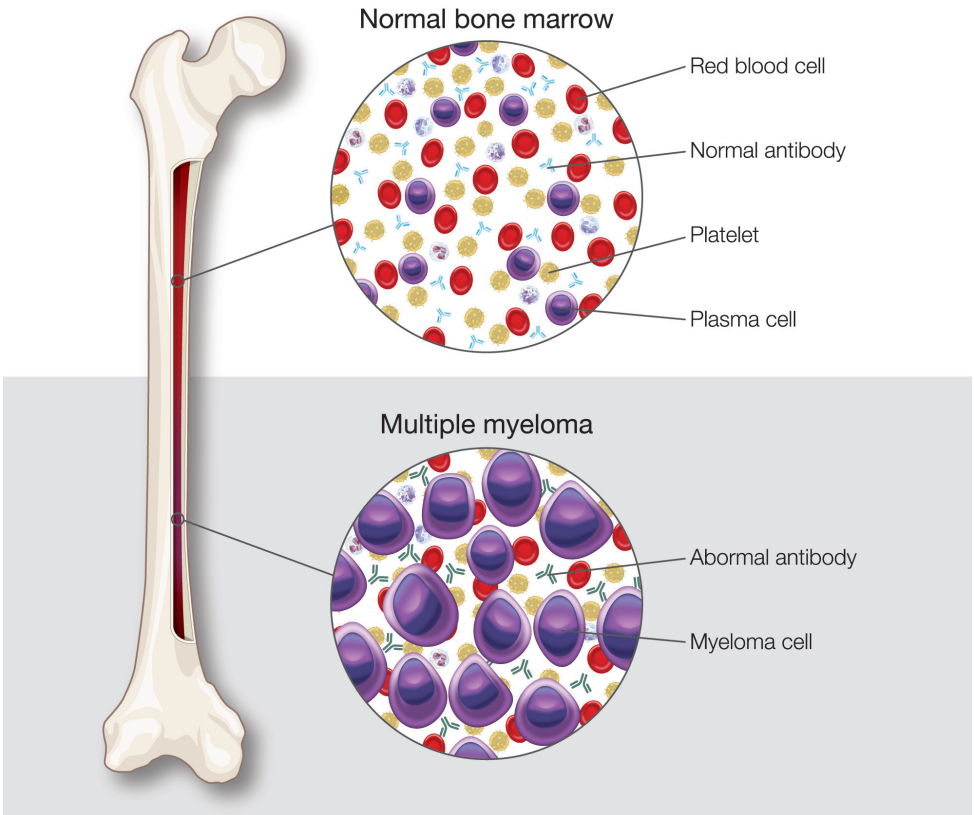
What is Multiple Myeloma?

Myeloma is a type of blood cancer that develops from plasma cells (a type of white blood cell) found in the bone marrow.[2]

Plasma cells are part of the immune system and help fight infection.

When they are cancerous, the abnormal plasma cells spread throughout the bone marrow so that there is not enough space to make enough normal blood cells.[2]

Myeloma is often called multiple myeloma because most people have multiple bone lesions at the time it is diagnosed.[2]



How Do I take Pomolide™?[1]

Ask your doctor if Pomolide™ is right for you. Your doctor will tell you how much Pomolide™ to take and for how long you will need to take it. They will monitor your progress and may adjust your dose or stop your treatment based on the results of your blood tests and on your general condition. Follow the instructions provided and use Pomolide™ until your doctor tells you to stop.

Swallow the capsules whole with a full glass of water, once a day, about the same time each day, as directed by your doctor. Pomolide™ can be taken with or without food.

Use strictly as directed. More information can be found in the Pomolide™ Consumer Medicine Information, which is available from your doctor or pharmacist.

Special handling:

Pomolide™ capsules should not be opened, broken, chewed, or crushed. If powder from Pomolide™ contacts the skin, wash the skin immediately and thoroughly with soap and water.

If pomalidomide contacts the mucous membranes e.g. the eyes, flush thoroughly with water.

Healthcare professionals, caregivers, or family members should wear disposable gloves and remove gloves carefully to prevent skin exposure when handling Pomolide™.

Females who are pregnant or suspect pregnancy should not handle Pomolide™.

Missing a dose[1]

If you forget to take Pomolide™ and it is less than 12 hours before your next dose, skip the dose you missed and take your next dose when you are meant to.

Otherwise, take it as soon as you remember, and then go back to taking your medicine as you would normally.

Do not take a double dose to make up for the dose that you missed.

Important Information about Pregnancy[1]

Pomalidomide is structurally related to 'thalidomide', which is known to cause severe life-threatening human birth defects and death to an unborn baby if taken during pregnancy.

If pomalidomide is taken during pregnancy, it may also cause birth defects or death to an unborn baby.

All patients, including those who cannot become pregnant, must be enrolled by their doctor in *Juno's Pregnancy Prevention Program*, to ensure that Pomolide™ is used safely.

Your doctor will provide you with specific instructions to help avoid potential effects of pomalidomide on unborn babies. Follow these instructions carefully. If you have not fully understood these instructions, ask your doctor to explain them again before you begin to take Pomolide™.

If you are not sure whether you should start taking this medicine, talk to your doctor.

Juno's Pregnancy Prevention Program[1] (PPP)

To avoid exposure to unborn babies, Pomolide™ is only available under a special program called the *Juno Pregnancy Prevention Program*.

This program is designed to ensure that Pomolide™ is always prescribed and taken in the recommended way. Importantly, only patients who are formally enrolled in this program and agree to fully comply with all the requirements of this program can receive Pomolide™.

Some of the requirements of the Juno Pregnancy Prevention Program are outlined in the following section. Your doctor will discuss all the details with you.

PPP General Requirements for All Patients Taking Pomolide™

All patients taking Pomolide™ must be enrolled in Juno's Pregnancy Prevention Program for Pomolide™.

Juno's Pregnancy Prevention Program is coordinated through a secure online platform called 'Juno Connected™'. Your doctor will register you with Juno Connected™ and you may receive communications via email or text upon enrolment.

Your doctor will explain the risks and necessary precautions associated with the use of Pomolide™, you must acknowledge that you understand these.

Your doctor will explain that Pomolide™ may cause severe birth defects and death to an unborn baby if taken during pregnancy.

You should never give Pomolide™ to another person, even if they have the same condition as you. You should return any unused capsules to your pharmacist at the end of treatment.

You must not donate blood during therapy including dose interruptions, or for one week following discontinuation of Pomolide™. In Australia and New Zealand, patients with myeloma are permanently excluded from donating blood.

PPP Requirements for Females Taking Pomolide™

Before starting treatment with Pomolide™, your doctor will discuss your potential to become pregnant, even if you think this is unlikely e.g. if your periods have stopped. If your doctor determines that you are of 'childbearing potential', you must adhere to the following conditions of the Juno Pregnancy Prevention Program:

- Your doctor will discuss the potential risk to unborn babies if Pomolide™ is taken during pregnancy. You must acknowledge that you understand this risk and agree to immediately contact your doctor if you suspect or have become pregnant while taking Pomolide™.
- You must avoid pregnancy whilst taking Pomolide™, during dose interruptions, and for 4 weeks after stopping Pomolide™.
- You must use reliable means of contraception for at least 4 weeks before starting Pomolide™ treatment, during treatment and treatment interruption, and for at least 4 weeks after Pomolide™ treatment has stopped. Your doctor will provide advice on what method of contraception to use.
- You will be required to have medically supervised pregnancy tests before treatment with Pomolide™, every 4 weeks during treatment, and 4 weeks after stopping treatment.
- You must collect your prescription from the pharmacy within 7 days of your negative pregnancy test.

You must stop taking Pomolide™ and inform your doctor straight away if:

- You miss or think you have missed a period, or you have unusual menstrual bleeding, or suspect you are pregnant.
- You have heterosexual intercourse without using reliable means of contraception.

PPP Requirements for Males Taking Pomolide™

Before starting treatment with Pomolide™, discuss with your doctor if your partner is able to become pregnant, as clinical data has demonstrated the presence of pomalidomide in human semen.

Your doctor will discuss the potential risk to unborn babies if Pomolide™ is taken during pregnancy. You must acknowledge that you understand this risk.

You must not donate semen during treatment, during treatment interruption, or for 1 week after stopping treatment.

If your partner is able to become pregnant, you must comply with the following additional conditions of the Juno Pregnancy Prevention Program:

- You must use barrier methods of contraception (e.g. condoms) even if you are vasectomised, during treatment with Pomolide™, during treatment interruption, and for at least 1 week after treatment has stopped.
- **You must tell your doctor immediately if your partner becomes pregnant whilst you are taking or within 1 week of stopping this medicine.**

Other things to be aware of[1]

Keep all of your doctor's appointments so that your progress can be checked. Your doctor will do some tests (blood tests) regularly to make sure the medicine is working and to prevent unwanted side effects.

Breastfeeding:

- It is not known if Pomolide™ is excreted in human milk. Therefore, you should discuss with your doctor whether to discontinue breast-feeding while you are receiving this medicine.

Other medicines:

- Speak to your prescribing doctor about any other medications you are currently taking, including any supplements.
- Tell any other doctors, dentists, and pharmacists who are treating you that you are taking Pomolide™, particularly if you are about start taking a new medication.

Driving or using machines:

- Be careful before you drive or use any machines or tools until you know how Pomolide™ affects you.
- Pomolide™ may cause dizziness or confusion in some people. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.

Drinking alcohol:

- Tell your doctor if you drink alcohol, as alcohol may interfere with the way this medicine works.

Side effects:

Like all medicines, side effects may be experienced with Pomolide™ treatment, although not everybody gets them. Some side effects are more common than others and some are more serious than others.

Do not be alarmed by the following list of side effects. You may not experience any of them.

The below list mainly includes the more common side effects of your medicine. Tell your doctor if you notice any of the following and they worry you:

- Constipation, diarrhoea, feeling sick (nausea), vomiting, decrease in appetite, pain in the lower abdomen or pelvic area, gastrointestinal bleeding.
- Itchiness or rash.
- Dizziness or spinning sensation, shaking or tremors, feeling faint or confused.
- Bone pain or muscle spasms.

The table below includes serious side effects that may require medical attention. Tell your doctor immediately if you notice the following:

Symptom	Possible reason
Heart palpitations or fast heartbeat, chest pains, dizziness or fainting, shortness of breath, weakness or reduced ability to exercise.	These could be symptoms of atrial fibrillation (irregular heartbeat).
Bleeding or bruising more easily than normal.	Pomolide can reduce the number of platelets, which are responsible for making the blood clot properly. Your doctor will monitor your blood cell numbers during treatment with Pomolide and do some blood tests regularly and will check your general condition to make sure the medicine is working and may adjust your dose accordingly.
Tiredness, headaches, shortness of breath, dizziness and looking pale.	Pomolide can reduce the number of red blood cells that carry oxygen around the body.
Chest pain, severe weakness, rapid or irregular heartbeat, and/or sudden, severe shortness of breath.	This could be due to heart failure, a condition where the heart muscle cannot pump blood strongly enough to supply blood throughout the body.
Numbness, tingling, abnormal co-ordination or pain in your hands and feet.	This may be due to nerve damage.
Blurred, loss of or double vision, difficulty speaking, weakness in an arm or a leg, a change in the way you walk or problems with your balance, persistent numbness, decreased sensation or loss of sensation, memory loss or confusion.	These may be symptoms of a serious and potentially fatal brain condition known as progressive multifocal leukoencephalopathy (PML).
Fever, severe chills, rapid breathing, shortness of breath, rapid pulse, confusion, nausea, vomiting, diarrhoea, pain or burning when you urinate, cough, phlegm, sore mouth or throat, or mouth ulcers.	These could be symptoms of a blood infection or other serious infection such as pneumonia.

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If symptoms continue or you have side effects, see your doctor, pharmacist or healthcare professional. To find further information on the risk and benefits of this medicine, speak to your pharmacist and please review the Consumer Medicine Information (CMI) available at the MedSafe website https://www.medsafe.govt.nz/Consumer/CMI/p/pomolide.pdf.

Pomolide™ is funded under restricted criteria for relapsed/refractory multiple myeloma. Normal doctor's charges may apply and a pharmacy charge will apply.

To report adverse events, please contact:
Juno Pharmaceuticals NZ Limited
Phone: 0800 857 030
Email: medical-enquiries@junopharm.com.au

REFERENCES: 1. Pomolide™ Consumer Medicine Information. 2. Cancer Council "What is myeloma?" Available from: https://www.cancer.org.au/cancer-information/types-of-cancer/myeloma, accessed 30/6/22. 3. Leukemia Foundation. "Myeloma" Available from https://www.leukaemia.org.au/blood-cancer-information/types-of-blood-cancer/myeloma/, accessed 30/06/22.

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