

# Pomolide capsules

## Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about taking this medicine, speak to your doctor or pharmacist.

**WARNING:** Important safety information is provided in a boxed warning in the [full CMI](#). Read before taking this medicine.

### 1. Why am I taking Pomolide?

Pomolide contains the active ingredient pomalidomide. Pomolide is used in combination with another medicine called 'dexamethasone' (steroid medicine) to treat adult patients diagnosed with Multiple Myeloma (MM) (a cancer of the bone marrow). It is prescribed for patients whose disease has progressed after two prior therapies.

For more information, see Section [1. Why am I taking Pomolide?](#) in the full CMI.

### 2. What should I know before I take Pomolide?

Do not use if you have ever had an allergic reaction to pomalidomide or any of the ingredients listed at the end of the CMI.

**Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.**

For more information, see Section [2. What should I know before I take Pomolide?](#) in the full CMI.

### 3. What if I am taking other medicines?

Some medicines may interfere with Pomolide and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

### 4. How do I take Pomolide?

Your doctor will tell you how much Pomolide to take and for how long you will need to take it, 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 as directed by your doctor.

Pomolide can be taken with or without food. Do not open, break or chew the capsules. If powder from the capsules contact 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.

More instructions can be found in Section [4. How do I take Pomolide?](#) in the full CMI.

### 5. What should I know while taking Pomolide?

<b>Things you should do</b>	<ul style="list-style-type: none"><li>Remind any doctor, dentist or pharmacist you visit that you are taking Pomolide.</li><li>Ensure that you or your partner do not get pregnant while you are on Pomolide.</li><li>Ensure that you participate in the Pregnancy Prevention Program conducted by Juno.</li></ul>
<b>Things you should not do</b>	Do not stop taking this medicine unless your doctor advises you to or you suspect or are pregnant.
<b>Driving or using machines</b>	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.
<b>Drinking alcohol</b>	Alcohol may interfere with the way this medicine works.
<b>Looking after your medicine</b>	<ul style="list-style-type: none"><li>Keep your capsules in a cool dry place where the temperature stays below 25°C.</li><li>Keep your capsules in the original pack until it is time to use them.</li><li>Keep this medicine where children cannot reach it.</li></ul>

For more information, see Section [5. What should I know while taking Pomolide?](#) in the full CMI.

### 6. Are there any side effects?

If you see any symptoms of an allergic reaction, sudden pain in chest or difficulty in breathing, rapid or irregular heart beat, pain or swelling in your legs, fever, chills, nausea, vomiting, diarrhoea or any jaundice like symptoms, stop taking Pomolide and see a doctor immediately or go to Accident and Emergency at your nearest hospital.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

**WARNING:**

Pomolide (pomalidomide) is structurally related to 'thalidomide', which is known to cause severe life-threatening human birth defects (deformed babies) and death to an unborn baby if taken during pregnancy. If Pomolide is taken during pregnancy, it may cause birth defects or death to an unborn baby. Do not take Pomolide if you are pregnant, or think that you are pregnant.

# Pomolide\*

Active ingredient(s): [pomalidomide]

## Consumer Medicine Information (CMI)

This leaflet provides important information about taking Pomolide. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about taking Pomolide.**

Where to find information in this leaflet:

- [1. Why am I taking Pomolide?](#)
- [2. What should I know before I take Pomolide?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I take Pomolide?](#)
- [5. What should I know while taking Pomolide?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

## 1. Why am I taking Pomolide?

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

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

## 2. What should I know before I take Pomolide?

### Warnings

Do not take Pomolide if:

- you are allergic to pomalidomide, or any of the ingredients listed at the end of this leaflet.
- Always check the ingredients to make sure you can take Pomolide.
- you are pregnant, or think that you are pregnant. Pomolide may cause birth defects (deformed babies), and may affect your developing baby if you take it during pregnancy.
- you are able to become pregnant, unless you are willing to follow the required pregnancy prevention

measures (outlined in Juno's Pregnancy Prevention program.

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

### Follow your doctor's instructions carefully.

You will have been given specific instructions by your doctor particularly on the potential effects of pomalidomide on unborn babies.

**If you have not fully understood these instructions, ask your doctor again before taking Pomolide.**

Your doctor will have enrolled you in Juno's Pregnancy Prevention program to ensure that pomalidomide is used safely.

### Check with your doctor if you:

- have any other medical conditions:
  - Blood clots
  - Frequent bleeding or bruising
  - Frequent infections
  - Peripheral neuropathy (numbness, tingling, weakness, abnormal coordination or pain in your hands and feet)
  - Abnormal kidney function
  - Allergic reactions to thalidomide or lenalidomide
  - Hepatitis B virus infection.
- take any medicines for any other condition
- Do not donate blood during Pomolide treatment or during treatment interruption, and for at least 1 week after stopping treatment.

In Australia and New Zealand, patients with myeloma are permanently excluded from donating blood.

- Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.
- Tell your doctor if you smoke.

Smoking may affect Pomolide or may affect how it works.

- Your doctor will ask you to have regular blood tests during treatment with Pomolide.

Your doctor may adjust your dose of Pomolide or stop your treatment based on the results of your blood tests and on your general condition.

- Do not give this medicine to a child or adolescent under the age of 18 years.

Safety and effectiveness in children younger than 18 years have not been established.

It is important to note that a small number of patients with multiple myeloma may develop additional types of cancer (regardless of their type of therapy). At this stage, it cannot be excluded that this risk may be slightly increased with Pomolide treatment. Therefore, your doctor will carefully evaluate the benefit and risk when you are prescribed this medicine. Superficial skin cancers have been observed in a small number of multiple myeloma patients treated with Pomolide.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

## Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

### *Juno's Pregnancy Prevention Program:*

Pomolide (pomalidomide) is structurally related to 'thalidomide', which is known to cause severe life-threatening human birth defects (deformed babies) and death to an unborn baby if taken during pregnancy. If Pomolide is taken during pregnancy, it may cause birth defects or death to an unborn baby.

To avoid exposure to unborn babies, Pomolide is available only under a special distribution program called the Juno Pregnancy Prevention program. This program is designed to ensure that this medicine 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 sections. Your doctor will discuss all the details with you.

### 1. For women taking Pomolide

**Before starting this treatment, your doctor will discuss your potential to become pregnant, even if you think this is unlikely e.g. if your periods have stopped.**

**Follow instructions below if you are able to become pregnant:**

- Your doctor will discuss the potential risk to unborn babies if Pomolide is taken during pregnancy.
- You will be required to have pregnancy tests before treatment, every 4 weeks during treatment, and 4 weeks after stopping treatment.
- Take Pomolide medicine as soon as you get it from the pharmacy following a negative pregnancy test.
- **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 tell you what method of contraception to use.

**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.

**Discuss with your doctor if you should breast-feed whilst taking this medicine.**

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.

### 2. For men taking Pomolide

**Before starting this treatment, discuss with your doctor if your partner is able to become pregnant.**

**If your partner is able to become pregnant, use barrier methods of contraception (e.g. condoms) even if you are vasectomised, during Pomolide treatment, during treatment interruption, and for at least 1 week after treatment has stopped.**

**Tell your doctor immediately if your partner becomes pregnant whilst you are taking this medicine.**

**Do not donate semen during treatment or during treatment interruption, or for 1 week after stopping treatment.**

## What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Tell your doctor if you are taking medications used to treat depression or obsessive compulsive disorder (OCD).

**Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Pomolide.**

## How do I take Pomolide?

### How much to take / use

- Your doctor will tell you how much Pomolide to take and for how long you will need to take it. Your doctor will monitor your progress and may adjust your dose.
- Your doctor may adjust your dose of Pomolide 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.

### When to take / use Pomolide

Pomolide should be used at about the same time each day. If you are on dialysis, on dialysis days take your medicine after dialysis.

### How to take Pomolide

- Swallow the capsules whole with a full glass of water, once a day as directed by your doctor.
- Pomolide can be taken with or without food.
- Do not open, break or chew the capsules.

If powder from the capsules contact 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.

### If you forget to use Pomolide

Pomolide should be used regularly at the same time each day. If you miss your dose at the usual time, skip the dose that has been missed if it is less than 12 hours before the next dose, and take the 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 you missed.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering when to take your medicine, ask your pharmacist for some hints.

### If you take too much of Pomolide

If you think that you have used too much Pomolide, you may need urgent medical attention.

### You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26 if you are in Australia), or
- phone the National Poisons Information Centre (by calling 0800 POISON or 0800 764 766 if you are in New Zealand), or contact your doctor, or

- go to the Emergency Department at your nearest hospital.

**You should do this even if there are no signs of discomfort or poisoning.**

## 5. What should I know while taking Pomolide?

### Things you should do

Female patients:

- Tell your doctor immediately if you suspect that you may be pregnant. You should also immediately stop taking Pomolide in this case.

All patients:

- Tell any other doctors, dentists, and pharmacists who are treating you that you are taking Pomolide.
- Tell your doctor if you have Hepatitis like symptoms. Hepatitis B virus status should be established before initiating treatment with pomalidomide.
- Tell your doctor if you have been diagnosed with Progressive Multifocal Leukoencephalopathy.

If you are about to be started on any new medicine, remind your doctor, dentist or pharmacist that you are taking Pomolide.

- 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.

### Call your doctor straight away if you:

- find out or suspect that you or your partner is pregnant.

Remind any doctor, dentist or pharmacist or any other healthcare professional you visit that you are taking Pomolide.

### Things you should not do

Female patients:

- Do not become pregnant whilst taking Pomolide.

Male patients:

- Do not donate semen during treatment or treatment interruption, or for at least 1 week after stopping treatment.

All patients:

- Do not have sexual intercourse without using effective means of contraception described to you by your doctor.

- Do not donate blood during treatment or treatment interruption, or for at least 1 week after stopping treatment.

In Australia and New Zealand, patients with myeloma are permanently excluded from donating blood.

- Do not stop taking Pomolide (unless you suspect that you are pregnant) or change the dose without first checking with your doctor.
- Do not let yourself run out of medicine over the weekend or on holidays.
- Do not give this medicine to anyone else, even if they have the same condition as you.
- Do not take this medicine to treat any other complaints unless your doctor or pharmacist tells you to.
- Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.
- In that case, return it to your pharmacist.

### 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.**

Alcohol may interfere with the way this medicine works.

### Looking after your medicine

- Keep your capsules in a cool dry place where the temperature stays below 25°C.
- Keep your capsules in the original pack until it is time to use them.
- Keep this medicine where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

**Keep it where young children cannot reach it.**

### When to discard your medicine (as relevant)

If your doctor tells you to stop taking this medicine or the expiry date has passed, take any unused Pomolide capsules to your pharmacist.

### Getting rid of any unwanted medicine

Medicines should not be disposed of via wastewater or household waste. These measures will help to protect the environment.

Do not use this medicine after the expiry date.

## 6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

### Less serious side effects

Less serious side effects	What to do
<ul style="list-style-type: none"> <li>Constipation, diarrhoea, feeling sick (nausea), vomiting, decrease in appetite, pain in the lower abdomen or pelvic area, gastrointestinal bleeding.</li> <li>Itchiness or rash.</li> <li>Dizziness or spinning sensation, shaking or tremors, feeling faint or confused.</li> <li>Bone pain or muscle spasms.</li> </ul>	<p><b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b></p>

### Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"> <li>Heart palpitations or fast heartbeat, chest pains, dizziness or fainting, shortness of breath, weakness or reduced ability to exercise.</li> </ul> <p>These could be symptoms of atrial fibrillation (irregular heartbeat).</p> <ul style="list-style-type: none"> <li>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</li> </ul>	<p><b>Call your doctor straight away.</b></p>

<p>will monitor your blood cell numbers during treatment with Pomolide.</p> <ul style="list-style-type: none"> <li>• Tiredness, headaches, shortness of breath, dizziness and looking pale Pomolide can reduce the number of red blood cells that carry oxygen around the body.</li> <li>• Chest pain and dry cough This may be due to a chest infection e.g. pneumonia.</li> <li>• Wheezing, shortness of breath or a chronic cough These may be symptoms caused by inflammation of the connective tissues in the lungs.</li> <li>• Numbness, tingling, abnormal co-ordination or pain in your hands and feet This may be due to nerve damage</li> </ul>	
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<p>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.</p> <ul style="list-style-type: none"> <li>• Pain or swelling in your legs, especially in your lower leg or calves. This may be due to blood clots in the veins of your leg. These can happen during treatment, or after treatment has stopped.</li> <li>• 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 sepsis (blood infection) or other serious infections such as pneumonia.</li> <li>• Passing little or no urine, drowsiness, nausea, vomiting or breathlessness. These could be symptoms of kidney disease.</li> <li>• Yellowing of the skin and/or eyes. These are symptoms of jaundice which can result from liver failure or a liver disease called hepatitis.</li> </ul>	
<ul style="list-style-type: none"> <li>• 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)</li> </ul>	<p><b>If any of the following happens, stop taking Pomolide and tell your doctor immediately.</b></p>

### Very serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"> <li>• Shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing; swelling of other parts of the body; rash, itching or hives on the skin; flaking or peeling of the skin. These could be symptoms of an allergic reaction.</li> <li>• Severe blisters and bleeding in the lips, eyes, mouth, nose and genitals; painful red area on the skin that spreads quickly; peeling of the skin. You may have a high temperature, chills and muscle ache at the same time. These could be due to rare but severe skin reactions such as Stevens-Johnson Syndrome, Toxic Epidermal Necrolysis and Drug Reaction with Eosinophilia and Systemic Symptoms.</li> <li>• Sudden pain in your chest or difficulty in breathing This may be due to blood clots in the artery leading to your lungs. These can happen during treatment, or after treatment has stopped.</li> <li>• Chest pain, severe weakness, rapid or irregular heartbeat,</li> </ul>	<p><b>If any of the following happens, stop taking Pomolide and go to Accident and Emergency at your nearest hospital</b></p>

**Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.**

Other side effects not listed here may occur in some people.

### Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at [www.tga.gov.au/reporting-problems](http://www.tga.gov.au/reporting-problems). By reporting side

effects, you can help provide more information on the safety of this medicine.

**Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.**

## 7. Product details

This medicine is only available with a doctor's prescription.

### What Pomolide contains

Active ingredient (main ingredient)	Pomalidomide
Other ingredients (inactive ingredients)	<ul style="list-style-type: none"><li>• mannitol,</li><li>• Croscarmellose Sodium</li><li>• pregelatinized starch, and</li><li>• sodium stearyl fumarate.</li></ul> <p>The capsule shells contain gelatin, purified water, titanium dioxide and the following colourants: 1 mg: FD&amp;C Blue 2 and yellow iron oxide; 2 mg: FD&amp;C Blue 2, yellow iron oxide and FD&amp;C Red 3; 3 mg: FD&amp;C Blue 2, yellow iron oxide and 4 mg: FD&amp;C Blue 2 .</p> <p>The white ink contains Shellac, Ethanol, isopropyl alcohol, n-Butanol, titanium dioxide, potassium hydroxide, propylene glycol, purified water and strong ammonia solution.</p> <p>The black ink contains Shellac, dehydrated alcohol, isopropyl alcohol, butyl alcohol, iron oxide black, propylene glycol, potassium hydroxide, purified water and strong ammonia solution.</p>
Potential allergens	Does not contain lactose.

**Do not take this medicine if you are allergic to any of these ingredients.**

### What Pomolide looks like

The capsules are provided in packs. A pack will contain three blisters, each with seven capsules, giving a total of twenty-one (21) capsules per pack.

Pomolide 1 mg are a hard gelatin capsules with a dark blue cap and a yellow body printed with 'NAT' in white ink on the cap and '1 mg' in black ink on the body of the capsule. (TT50-11110)

Pomolide 2 mg are a hard gelatin capsules with a dark blue cap and an orange body printed with 'NAT' in white ink on its cap and '2 mg' in white ink on the body of the capsule. (TT50-11110a)

Pomolide 3 mg are a hard gelatin capsules with a dark blue cap and a green body printed with white ink on its body. (TT50-11110b)

Pomolide 4 mg are a hard gelatin capsules with a dark blue cap and a blue body printed with white ink on its body (TT50-11110c)

### Who distributes Pomolide

Juno Pharmaceuticals NZ Ltd,  
RSM New Zealand (Auckland),  
RSM House, Level 2,  
62 Highbrook Drive,  
East Tamaki,  
Auckland, 2013,  
New Zealand

For Medical Information please call 0800 816 921

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