

POMALYST®

Consumer Medicine Information (CMI) summary

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

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

1. Why am I using POMALYST?

POMALYST contains the active ingredient pomalidomide. POMALYST 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.

POMALYST is also used in combination with dexamethasone and another medicine called 'bortezomib' to treat adult MM patients whose disease has progressed after one therapy. For more information, see Section [1. Why am I using POMALYST?](#) in the full CMI.

2. What should I know before I use POMALYST?

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 use POMALYST?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with POMALYST 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 use POMALYST?

Your doctor will tell you how much POMALYST 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 all directions given to you by your doctor carefully. They may differ from the information contained in this leaflet.

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

5. What should I know while using POMALYST?

Things you should do	<ul style="list-style-type: none">● Remind any doctor, dentist or pharmacist you visit that you are using POMALYST.● If you are a female patient, tell your doctor immediately if you suspect that you may be pregnant. You should also immediately stop taking POMALYST in this case.
Things you should not do	<ul style="list-style-type: none">● Do not stop taking POMALYST (unless you suspect that you are pregnant) or change the dose without first checking with your doctor.● Do not become pregnant or breastfeed whilst taking POMALYST.● Do not donate sperm during treatment or for

	<p>1 week after stopping treatment.</p> <ul style="list-style-type: none"> • Do not have sexual intercourse without using effective means of contraception. • Do not donate blood during treatment or for 1 week after stopping treatment.
Driving or using machines	<ul style="list-style-type: none"> • POMALYST 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.
Looking after your medicine	<ul style="list-style-type: none"> • 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.

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

6. Are there any side effects?

You may experience serious side effects when taking POMALYST.

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: POMALYST (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 POMALYST is taken during pregnancy, it may cause birth defects or death to an unborn baby. Do not take POMALYST if you are pregnant or think that you are pregnant.

POMALYST® (POM-uh-list)

Active ingredient(s): [*pomalidomide*] (poe" ma lid' oh mide)

Consumer Medicine Information (CMI)

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

Where to find information in this leaflet:

- [1. Why am I using POMALYST?](#)
- [2. What should I know before I use POMALYST?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use POMALYST?](#)
- [5. What should I know while using POMALYST?](#)

[6. Are there any side effects?](#)

[7. Product details](#)

1. Why am I using POMALYST?

POMALYST contains the active ingredient pomalidomide.

POMALYST belongs to a group of medicines called immunomodulating agents.

POMALYST 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.

POMALYST is also used in combination with dexamethasone and another medicine called 'bortezomib' to treat adult MM patients whose disease has progressed after one therapy.

Ask your doctor if you have any questions about how Pomalyst works or why this medicine has been prescribed for you.

Your doctor may have prescribed it for another reason.

This medicine is not addictive.

Pomalyst will only be prescribed to you by a doctor who has experience in medicines to treat cancers of the blood.

2. What should I know before I use POMALYST?

Warnings

Do not use POMALYST 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 use this medicine.
- You are pregnant or think that you are pregnant. POMALYST 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 the i-access® program - see section 'The i-access 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.

Check with your doctor if you:

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

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.

The i-access program

Your doctor will have enrolled you in the i-access program to ensure that pomalidomide is used safely.

POMALYST (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 POMALYST is taken during pregnancy, it may cause birth defects or death to an unborn baby.

To avoid exposure to unborn babies, POMALYST has restricted availability under a Pregnancy Prevention Program (i-access). 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 POMALYST.

Some of the requirements of the i-access program are outlined in the following sections. Your doctor will discuss all the details with you.

1. For women taking POMALYST

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 POMALYST 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 POMALYST 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 POMALYST treatment, during treatment and treatment interruption, and for at least 4 weeks after POMALYST treatment has stopped.

Your doctor will tell you what method of contraception to use.

Effective methods of contraception include the following:

- 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 are not recommended as they can increase the risk of blood clots blocking blood vessels in patients with MM being treated with this medicine.

You must stop taking POMALYST 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 POMALYST 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 POMALYST

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 POMALYST 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.

3. For all patients taking POMALYST

Discuss with your doctor if you have or have had any of the following medical conditions:

- Blood clots
- Frequent bleeding or bruising
- Frequent infections
- Peripheral neuropathy (numbness, tingling, weakness, abnormal co-ordination or pain in your hands and feet)
- Abnormal kidney function
- Allergic reactions to thalidomide or lenalidomide
- Hepatitis B virus infection.

If you have not told your doctor about any of the above, tell him/her before you start taking POMALYST.

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

In Australia, 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 POMALYST or may affect how it works.

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

Your doctor may adjust your dose of POMALYST 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 POMALYST 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 POMALYST.

3. What if I am taking other medicines?

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

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

Some of these medicines and POMALYST may interfere with each other.

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

4. How do I use POMALYST?

How much to take/use

Follow all directions given to you by your doctor carefully. They may differ from the information contained in this leaflet.

- Your doctor will tell you how much POMALYST 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 POMALYST or stop your treatment based on the results of your blood tests and on your general condition.

When to take / use POMALYST

- Take your medicine at about the same time each day. If you are on dialysis, on dialysis days take your medicine after dialysis.

How to take POMALYST

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

If you forget to use POMALYST

- If 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.
- 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 use too much POMALYST

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

You should immediately:

- In Australia, phone the Poisons Information Centre (**by calling 13 11 26**), or
- In New Zealand, phone the National Poisons Centre (by calling 0800 POISON or 0800 764 766)
- 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 using POMALYST?

Things you should do

Female patients:

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

All patients:

- Tell any other doctors, dentists, and pharmacists who are treating you that you are taking POMALYST.

- If you are about to start any new medicine, remind your doctor, dentist, or pharmacist that you are taking POMALYST.
- Keep all 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.

Things you should not do

Female patients:

- **Do not become pregnant whilst taking POMALYST.**

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, patients with myeloma are permanently excluded from donating blood.

- Do not stop taking POMALYST (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 POMALYST affects you.

POMALYST 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 it where young children cannot reach it.

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

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

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

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.

Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"> ● Heart palpitations or fast heartbeat, chest pains, dizziness or fainting, shortness of breath, weakness, or reduced ability to exercise. <p>These could be symptoms of atrial fibrillation (irregular heartbeat).</p> <ul style="list-style-type: none"> ● Bleeding or bruising more easily than normal <p>POMALYST 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 POMALYST.</p> <ul style="list-style-type: none"> ● Tiredness, headaches, shortness of breath, dizziness and looking pale 	<p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p>

Serious side effects	What to do
<p>POMALYST can reduce the number of red blood cells that carry oxygen around the body.</p> <ul style="list-style-type: none"> • Chest pain and dry cough <p>This may be due to a chest infection e.g., pneumonia.</p> <ul style="list-style-type: none"> • Wheezing, shortness of breath or a chronic cough <p>These may be symptoms caused by inflammation of the connective tissues in the lungs.</p> <ul style="list-style-type: none"> • Numbness, tingling, abnormal co-ordination or pain in your hands and feet <p>This may be due to nerve damage.</p> <ul style="list-style-type: none"> • Blurred, loss of or double vision, difficulty speaking, weakness in an arm or a leg, a change in the way you walk or 	

Serious side effects	What to do
<p>problems with your balance, persistent numbness, decreased sensation or loss of sensation, memory loss or confusion.</p> <p>These may be symptoms of a serious and potentially fatal brain condition known as progressive multifocal leukoencephalopathy (PML).</p> <ul style="list-style-type: none"> • 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. <p>These could be symptoms of an allergic reaction.</p> <ul style="list-style-type: none"> • Severe blisters and bleeding in the lips, eyes, mouth, nose 	

Serious side effects	What to do
<p>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.</p> <p>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.</p> <ul style="list-style-type: none"> • Sudden pain in your chest or difficulty in breathing <p>This may be due to blood clots in the artery leading to your lungs. These can happen during treatment, or after treatment has stopped.</p> <ul style="list-style-type: none"> • Chest pain, severe weakness, rapid or irregular heartbeat, 	

Serious side effects	What to do
<p>and/or sudden, severe shortness of breath.</p> <p>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"> • Pain or swelling in your legs, especially in your lower leg or calves <p>This may be due to blood clots in the veins of your leg. These can happen during treatment, or after treatment has stopped.</p> <ul style="list-style-type: none"> • 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. 	

Serious side effects	What to do
<p>These could be symptoms of sepsis (blood infection) or other serious infections such as pneumonia.</p> <ul style="list-style-type: none"> • Passing little or no urine, drowsiness, nausea, vomiting or breathlessness. <p>These could be symptoms of kidney disease.</p> <ul style="list-style-type: none"> • Yellowing of the skin and/or eyes. <p>These are symptoms of jaundice which can result from liver failure, or a liver disease called hepatitis.</p>	

Other side effects

Very common side effects	What to do
<ul style="list-style-type: none"> • Constipation, diarrhoea, feeling sick (nausea), vomiting, decrease in appetite, pain in the lower abdomen or pelvic 	<p>Speak to your doctor if you have any of these side effects and they worry you.</p>

Very common side effects	What to do
<p>area, gastrointestinal bleeding.</p> <ul style="list-style-type: none"> ● Itchiness or rash. ● Dizziness or spinning sensation, shaking or tremors, feeling faint or confused. ● Bone pain or muscle spasms. 	

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. 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 POMALYST contains

Active ingredient (main ingredient)	Pomalidomide
Other ingredients (inactive ingredients)	<ul style="list-style-type: none">• mannitol• pregelatinised starch• sodium stearyl fumarate. <p>The capsule shells contain gelatin, titanium dioxide and the following colourants:</p> <p>1 mg capsules: indigo carmine and yellow iron oxide.</p> <p>2 mg capsules: indigo carmine, yellow iron oxide and erythrosine.</p> <p>3 mg capsules: Indigo carmine and yellow iron Oxide.</p>

	<p>4 mg capsules: Indigo carmine and brilliant blue FCF</p> <p>The white ink contains Shellac, titanium dioxide, simethicone, propylene glycol and ammonium hydroxide/ strong ammonia solution</p> <p>The black ink contains: Shellac, Iron oxide black, propylene glycol 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 POMALYST looks like

The capsules are provided in packs. There are two (2) pack sizes available. A pack will contain either three blisters, each with seven capsules, giving a total of twenty-one (21) capsules per pack or two blisters, each with seven capsules, giving a total of fourteen (14) capsules per pack.

- POMALYST 1 mg capsules are yellow opaque body/ dark blue opaque cap capsules with "POML 1 mg" written on them. (AUST R 212657)

- POMALYST 2 mg capsules are orange opaque body/ dark blue opaque cap capsules with "POML 2 mg" written on them. (AUST R 212654)
- POMALYST 3 mg capsules are green opaque body/ dark blue opaque cap capsules with "POML 3 mg" written on them. (AUST R 212656)
- POMALYST 4 mg capsules are blue opaque body/ dark blue opaque cap capsules with "POML 4 mg" written on them. (AUST R 212655)

Who distributes POMALYST

Bristol-Myers Squibb Australia Pty Ltd

4 Nexus Court, Mulgrave

Victoria 3170, Australia

Toll free number: 1800 067 567

Email: MedInfo.Australia@bms.com

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This leaflet was prepared in January 2025.