

# Pomalidomide Sandoz®

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

### 1. Why am I taking Pomalidomide Sandoz?

Pomalidomide Sandoz contains the active ingredient pomalidomide. Pomalidomide Sandoz is used to treat adult patients diagnosed with Multiple Myeloma (MM) (a cancer of the bone marrow) whose disease has progressed after prior therapies. For more information, see Section [1. Why am I taking Pomalidomide Sandoz?](#) in the full CMI.

### 2. What should I know before I take Pomalidomide Sandoz?

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 Pomalidomide Sandoz?](#) in the full CMI.

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

Some medicines may interfere with Pomalidomide Sandoz 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 Pomalidomide Sandoz?

- Swallow the capsules whole with a full glass of water, once a day as directed by your doctor.
- Do not open, break or chew the capsules.

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

### 5. What should I know while taking Pomalidomide Sandoz?

<b>Things you should do</b>	<ul style="list-style-type: none"><li>• Remind any doctor, dentist or you visit that you are using Pomalidomide Sandoz.</li><li>• If you become pregnant while you are taking this medicine, stop taking it and tell your doctor or pharmacist immediately.</li></ul>
<b>Things you should not do</b>	<ul style="list-style-type: none"><li>• Do not stop using this medicine or change the dose without checking with your doctor.</li><li>• Do not become pregnant, donate semen or have sexual intercourse without using effective means of contraception described to you by your doctor.</li><li>• Do not donate blood.</li></ul>
<b>Driving or using machines</b>	<ul style="list-style-type: none"><li>• Be careful before you drive or use any machines until you know how Pomalidomide Sandoz affects you.</li></ul>
<b>Looking after your medicine</b>	<ul style="list-style-type: none"><li>• Keep the medicine 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 take them.</li></ul>

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

### 6. Are there any side effects?

You may experience serious side effects when taking Pomalidomide Sandoz.

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

# Pomalidomide Sandoz®

Active ingredient(s): *pomalidomide*

## Consumer Medicine Information (CMI)

This leaflet provides important information about using Pomalidomide Sandoz. **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 Pomalidomide Sandoz.**

**Where to find information in this leaflet:**

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

## 1. Why am I taking Pomalidomide Sandoz?

**Pomalidomide Sandoz contains the active ingredient pomalidomide.**

Pomalidomide Sandoz is an immunomodulating agent. Pomalidomide Sandoz 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.

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

## 2. What should I know before I take Pomalidomide Sandoz?

### Warnings

**Do not take Pomalidomide Sandoz 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.
- are pregnant or plan to become pregnant

**Check with your doctor if you:**

- have any other medical conditions especially the following: 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, or hepatitis B virus infection.

**Tell your doctor if you smoke.** Smoking may affect Pomalidomide Sandoz or may affect how it works.

**Do not donate blood during Pomalidomide Sandoz 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.

**Your doctor will ask you to have regular blood tests during treatment with Pomalidomide Sandoz.** Your doctor may adjust your dose of Pomalidomide Sandoz or stop your treatment based on the results of your blood tests and on your general condition.

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 Pomalidomide Sandoz 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 Pomalidomide Sandoz.

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

**Do not take this medicine if you are pregnant or intend to become pregnant.**

Pomalidomide Sandoz (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

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

Do not take this medicine if you are able to become pregnant, unless you are willing to follow the required pregnancy prevention measures (outlined in Pregnancy Prevention program).

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

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

## The Pregnancy Prevention program

To avoid exposure to unborn babies, Pomalidomide Sandoz is available only under a special distribution program called the 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 Pomalidomide Sandoz.

Some of the requirements of the Pregnancy Prevention program are outlined in the following sections. Your doctor will discuss all the details with you.

### 1. For women taking Pomalidomide Sandoz:

**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 Pomalidomide Sandoz 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 Pomalidomide Sandoz 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 Pomalidomide Sandoz treatment, during treatment and treatment interruption, and for at least 4 weeks after Pomalidomide Sandoz treatment has stopped.**  
Your doctor will tell you what method of contraception to use.

**You must stop taking Pomalidomide Sandoz 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 Pomalidomide Sandoz 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 Pomalidomide Sandoz:

**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 Pomalidomide Sandoz 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.**

## Children and adolescents

**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.

## 3. 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.

**Some medicines may interfere with Pomalidomide Sandoz and affect how it works.**

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

Some of these medicines and Pomalidomide Sandoz may interfere with each other.

Your doctor will monitor your progress and may adjust your dose.

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

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

## 4. How do I take Pomalidomide Sandoz?

### How much to take

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

### When to take Pomalidomide Sandoz

- Pomalidomide Sandoz should be taken at about the same time each day. If you are on dialysis, on dialysis days take your medicine after dialysis.

### How to take Pomalidomide Sandoz

- Swallow the capsules whole with a full glass of water.
- Do not open, break or chew the capsules. If the 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 take Pomalidomide Sandoz

Pomalidomide Sandoz should be used regularly at the same time each day.

**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, 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 use too much Pomalidomide Sandoz

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

#### You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26), 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 Pomalidomide Sandoz?

### Things you should do

#### Female patients:

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

#### All patients:

Remind any doctor, dentist or pharmacist you visit that you are using Pomalidomide Sandoz.

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

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 that medicine is working and to prevent unwanted side effects.

### Things you should not do

#### Female patients:

- Do not become pregnant whilst taking Pomalidomide Sandoz.

#### 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 Pomalidomide Sandoz (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 Pomalidomide Sandoz affects you.**

Pomalidomide Sandoz 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.**

## 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 take them.

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.**

## 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.

## 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</li> <li>• diarrhoea</li> <li>• feeling sick (nausea)</li> <li>• vomiting</li> <li>• decrease in appetite</li> <li>• pain in the lower abdomen or pelvic area</li> <li>• gastrointestinal bleeding</li> <li>• itchiness or rash</li> <li>• dizziness or spinning sensation</li> <li>• shaking or tremors</li> <li>• 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>• <b>Heart palpitations or fast heartbeat, chest pains, dizziness or fainting, shortness of breath, weakness or reduced ability to exercise.</b> These could be symptoms of atrial fibrillation (irregular heartbeat).</li> <li>• <b>Bleeding or bruising more easily than normal.</b> Pomalidomide Sandoz 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 Pomalidomide Sandoz.</li> <li>• <b>Tiredness, headaches, shortness of breath, dizziness and looking pale.</b> Pomalidomide Sandoz can reduce the number of red blood cells that carry oxygen around the body.</li> <li>• <b>Chest pain and dry cough.</b> This may be due to a chest infection e.g. pneumonia.</li> <li>• <b>Wheezing, shortness of breath or a chronic cough.</b> These may be symptoms caused by inflammation of the connective tissues in the lungs.</li> <li>• <b>Numbness, tingling, abnormal co-ordination or pain in your hands and feet.</b> This may be due to nerve damage.</li> <li>• <b>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.</b> These may be symptoms of a serious and potentially fatal brain condition known as progressive multifocal leukoencephalopathy (PML).</li> <li>• <b>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.</b> These could be symptoms of an allergic reaction.</li> </ul>	<p><b>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.</b></p>

- **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.

- **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.

- **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.

- **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.

- **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.

- **Passing little or no urine, drowsiness, nausea, vomiting or breathlessness.**

These could be symptoms of kidney disease.

- **Yellowing of the skin and/or eyes.**

These are symptoms of jaundice which can result from liver failure or a liver disease called hepatitis.

## 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 Pomalidomide Sandoz contains

<b>Active ingredient (main ingredient)</b>	pomalidomide
<b>Other ingredients (inactive ingredients)</b>	<ul style="list-style-type: none"> <li>• microcrystalline cellulose</li> <li>• maltodextrin</li> <li>• sodium stearyl fumarate</li> <li>• gelatin</li> <li>• titanium dioxide</li> <li>• iron oxide yellow (E172)</li> <li>• iron oxide red (E172)</li> <li>• indigotine – FD&amp;C Blue 2 (E132) (3 mg and 4 mg capsule only)</li> <li>• erythrosin – FD&amp;C Red 3 (E127) (4 mg capsule only)</li> </ul>

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

### What Pomalidomide Sandoz looks like

Pomalidomide Sandoz capsules comes in packs of 14 and 21 capsules.

Pomalidomide Sandoz 1 mg capsule is a yellow body/red cap capsule with "PML 1" written on them (AUST R 352569).

Pomalidomide Sandoz 2 mg capsule is an orange body/red cap capsule with "PML 2" written on them (AUST R 352570).

Pomalidomide Sandoz 3 mg capsule is a turquoise body/red cap capsule with "PML 3" written on them (AUST R 352571).

Pomalidomide Sandoz 4 mg capsule is a dark blue body/red cap capsule with "PML 4" written on them (AUST R 352572).

*\*not all strengths may be available*

**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.

## **Who distributes Pomalidomide Sandoz**

Pomalidomide Sandoz is supplied in Australia by:

Sandoz Pty Ltd

ABN 60 075 449 553

54 Waterloo Road

Macquarie Park, NSW 2113

Australia

Tel: 1800 726 369

This leaflet was prepared in September 2022.