

Lenalide capsules

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 Lenalide?

Lenalide contains the active ingredient Lenalidomide. It is used to treat patients with Multiple Myeloma, Myelodysplastic Syndromes (MDS) and newly diagnosed and previously treated Mantle Cell Lymphoma (MCL).

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

2. What should I know before I use Lenalide?

Do not use if you have ever had an allergic reaction to lenalidomide 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. It is extremely important that you get enrolled for the Pregnancy Prevention Program. You must take all precautions and measures to prevent pregnancy.

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

3. What if I am taking other medicines?

Some medicines may interfere with Lenalide 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 Lenalide?

- Your doctor will tell you how much Lenalide to take and for how long you will need to take it, monitor your progress and may adjust your dose. Based on the results of your blood tests and on your general condition. Swallow the capsules whole with a full glass of water, once a day as directed by your doctor.
- Lenalide should be taken either one hour before or two hours after eating 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 lenalidomide contacts the mucous membranes e.g. the eyes, flush thoroughly with water.

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

5. What should I know while using Lenalide?

Things you should do	<ul style="list-style-type: none">Remind any doctor, dentist or pharmacist you visit that you are using Lenalide.Ensure that you or your partner do not get pregnant while you are on Lenalide.
Things you should not do	<ul style="list-style-type: none">Do not stop using this medicine unless your doctor advises you to or you are or suspect that you are pregnant.If you are about to be started on any new medicine, remind your doctor, dentist or pharmacist that you are taking Lenalide.Keep all of your doctor's appointments so that your progress can be checked.
Driving or using machines	<ul style="list-style-type: none">Be careful before you drive or use any machines or tools until you know how Lenalide affects you.Lenalide may cause dizziness, blurred vision 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	<ul style="list-style-type: none">Alcohol may interfere with the way this medicine works.
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.Keep this medicine where children cannot reach it in a locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

For more information, see Section [5. What should I know while using Lenalide?](#) 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, frequent bleeding or bruising, pain or swelling in your legs, fever, chills, abdominal pain, passing of little or no urine, dark urine, yellowing of skin and/or eyes or any other unusual symptoms, stop taking Lenalide 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: Lenalide 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 Lenalide is taken during pregnancy, it may cause birth defects or death to an unborn baby. Do not take Lenalide if you are pregnant or think that you are pregnant.

Lenalide

Active ingredient(s): lenalidomide

Consumer Medicine Information (CMI)

This leaflet provides important information about using Lenalide. **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 Lenalide.**

Where to find information in this leaflet:

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

1. Why am I using Lenalide?

Lenalide contains the active ingredient lenalidomide. Lenalide belongs to a group of medicines called immunomodulating agents that work by acting on the cells involved in the body's immune system.

Lenalide is used to treat patients with Multiple myeloma (MM) (a cancer of the bone marrow).

Lenalide is also used to treat patients who have conditions called myelodysplastic syndromes (MDS) in whom the bone marrow does not produce enough mature blood cells. Lenalide is approved to treat a type of MDS where part of chromosome 5 is missing.

Lenalide is used to treat adult patients who have been diagnosed with and previously treated for Mantle Cell Lymphoma (MCL) (a cancer of lymph tissue).

2. What should I know before I use Lenalide?

Warnings

Do not use Lenalide if:

- you are allergic to lenalidomide, 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. Lenalide 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).

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.

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 lenalidomide on unborn babies.

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

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

It is extremely important that you get enrolled for the Pregnancy Prevention Program. You must take all precautions and measures to prevent pregnancy.

Check with your doctor if you:

- have any of the following medical conditions
 - Heart attack, blood clots, high blood pressure or high cholesterol
 - Frequent bleeding or bruising
 - Frequent infections
 - Hepatitis B virus infection
 - Peripheral neuropathy (numbness, tingling, weakness, abnormal coordination or pain in your hands and feet)
 - Thyroid problems
 - Abnormal kidney function
 - Liver problems e.g. liver infections
- You have had allergic reactions to thalidomide or lenalidomide.
- You take any medicines for any other condition

In Australia, patients with certain cancers are permanently excluded from donating blood.

- Do not take Lenalide if you have the rare hereditary problems of glucose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption. Lenalide contains lactose.
- Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

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 Lenalide treatment. Therefore, your doctor will carefully evaluate the benefit and risk when you are prescribed this medicine.

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

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

To avoid exposure to unborn babies, Lenalide 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 Lenalide.

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 Lenalide

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

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

If you are a female patient of childbearing potential, you must use one effective method of contraception for 4 weeks before therapy, during therapy, and until 4 weeks after Lenalide therapy, even in case of dose interruption, unless you can commit to absolute and continuous abstinence which can be confirmed on a monthly basis.

Recommended methods of contraception are:

- Contraceptive implant
- Levonorgestrel releasing intrauterine system (IUS)
- Medroxyprogesterone acetate depot
- Tubal ligation
- Sexual intercourse with a vasectomised male partner only
- 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 Lenalide 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 Lenalide 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 Lenalide

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 Lenalide 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 at least 1 week after stopping treatment.

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 Lenalide and affect how it works.

These include:

- medicines used to prevent pregnancy, such as oral contraceptives
- medicines used to treat symptoms of menopause e.g. hormone replacement therapy
- medicines used for heart problems e.g. digoxin
- medicines used to thin the blood e.g. warfarin.

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

4. How do I use Lenalide?

How much to take?

- Your doctor will tell you how much Lenalide 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 Lenalide or stop your treatment based on the results of your blood tests and on your general condition.
- Follow the instructions provided and use Lenalide until your doctor tells you to stop.

When to take Lenalide?

- Lenalide should be used either one hour before or two hours after eating food.

How to take Lenalide

- 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.
- If powder from the capsules contact the skin, wash the skin immediately and thoroughly with soap and water. If Lenalidomide contacts the mucous membranes e.g. the eyes, flush thoroughly with water.

If you forget to use Lenalide

Lenalide 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 use too much Lenalide

If you think that you have used too much Lenalide, 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 using Lenalide?

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 Lenalide in this case.

All patients:

- Tell any other doctors, dentists, and pharmacists who are treating you that you are taking Lenalide.
- If you are about to be started on any new medicine, remind your doctor, dentist or pharmacist that you are taking Lenalide.
- 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.

Your doctor may adjust your dose of Lenalide or stop your treatment based on the results of your blood tests and on your general condition. If you are older than 65 years, in addition to these blood tests, your doctor may also check your kidney function with other tests.

Call your doctor straight away if you:

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

Things you should not do

Female patients:

- Do not become pregnant whilst taking Lenalide.

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 certain cancers are permanently excluded from donating blood.

- Do not stop taking Lenalide (unless your doctor advises you to or you are, or suspect 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 Lenalide affects you.

Lenalide may cause dizziness, blurred vision or tiredness 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 away from moisture, heat or sunlight; where the temperature stays below 25°C for example, do not store it:

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

Keep it where young children cannot reach it.

When to discard your medicine

If your doctor tells you to stop taking this medicine or the expiry date has passed, take any unused Lenalide 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">• Diarrhoea; constipation; feeling sick (also called nausea); vomiting; stomach pain; indigestion; dehydration; dry mouth; sore mouth; mouth ulcers; difficulty in speaking; toothache; increase or decrease in weight; increase or decrease in appetite; loss of taste.• Itchiness; rash; redness of the skin; dry skin; bruising; excessive sweating.• Dizziness; fainting; headache; shaking or tremors; unusual weakness; night sweats; reduced sense of touch.• Difficulty sleeping; depression; anxiety; feeling of confusion.• Back pain; muscle spasms; muscle and/or joint pain; swollen joints; bone pain; muscular weakness; pain in the extremities; feeling tired; fall.• Swelling of hands, ankles or feet.	Speak to your doctor if you have any of these less serious side effects and they worry you.

Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none">○ Heart palpitations or fast heart beat, chest pains, dizziness or fainting, shortness of breath, weakness, or reduced ability to exercise.	Call your doctor straight away, or go straight to the Emergency Department at your nearest

<p>These could be symptoms of atrial fibrillation (irregular heart beat) or tachycardia (fast heart beat).</p> <ul style="list-style-type: none"> ○ Bleeding (including nosebleeds) or bruising more easily than normal. Lenalidomide can reduce the number of platelets, which are responsible for making the blood clot properly. Your doctor may monitor your blood cell numbers during treatment with Lenalidomide. ○ Tiredness, headaches, shortness of breath, dizziness and looking pale. Lenalidomide can reduce the number of red blood cells that carry oxygen around the body. ○ Numbness, tingling, pins and needles or weakness of the arms and legs. This may be due to nerve damage. ○ Blurred vision or difficulty seeing. This could be due to a cataract in your eye(s). ○ Passing large amounts of urine, excessive thirst, and having a dry mouth and skin. These could be symptoms of high blood sugar or diabetes. ○ Abnormal eye movements, convulsions, mood changes or irregular heart rhythms. These could be due to low levels of minerals such as potassium, calcium, magnesium or sodium. ○ Tender swollen lymph nodes, low-grade fever, pain, or rash. This could be due to worsening of your tumour (for patients with MCL). 	<p>hospital if you notice any of these serious side effects</p>
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<p>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.</p> <ul style="list-style-type: none"> • Blurred vision; severe headache; weakness or numbness in the face, arm or leg; trouble speaking or understanding; loss of balance. This may be due to a stroke which could be a result of blood clots in the blood vessels of your brain. • Sudden pain in your chest or difficulty in breathing. This may be due to a heart attack or blood clots in the artery leading to your lungs. These blood clots can happen during treatment, or after treatment has stopped. • Chest pain, severe weakness, rapid or irregular heartbeat, and/or sudden, severe shortness of breath and coughing up pink, foamy mucus. 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; decreased urination; rapid pulse; rapid breathing; confusion; nausea; vomiting; diarrhoea; pain or burning when you urinate; hacking cough; phlegm; sore mouth or throat; flu-like symptoms; feeling of tension in the nose, cheeks and behind your eyes; or mouth ulcers. These could symptoms of sepsis (blood infection) or other serious infections such as pneumonia. • Passing little or no urine; drowsiness; nausea; vomiting; or breathlessness. 	
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Very serious side effects

Very serious side effects	What to do
<ul style="list-style-type: none"> • Shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, mouth, tongue or other parts of the body; rash, itching or hives on the skin. These could be symptoms of an allergic reaction. • Severe blisters and bleeding in the lips, eyes, mouth, nose and genitals; painful red area on the skin that spreads quickly; peeling 	<p>If any of the following happens, stop taking Lenalide and see a doctor immediately or go to Accident and Emergency at your nearest hospital</p>

<p>These could be symptoms of kidney disease.</p> <ul style="list-style-type: none"> • Abdominal pain, dark urine, fever, joint pain, loss of appetite, nausea and vomiting, yellowing of the skin and/or eyes. <p>These are symptoms of liver failure, which in some cases, may be due to Hepatitis B virus infection. Some cases of Hepatitis B virus infection may not result in symptoms initially.</p>	
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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. Some side effects (for example, changes in thyroid function, or blood pressure) can only be found when your doctor does tests from time to time to check your progress.

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 Lenalide contains

Active ingredient (main ingredient)	Lenalidomide
Other ingredients (inactive ingredients)	<p>The other ingredients are:</p> <ul style="list-style-type: none"> • lactose <p>The capsule shells comprise of gelatin and titanium dioxide (E171), black ink and may also contain the following colourants:</p> <ul style="list-style-type: none"> • 20 mg capsules: FD&C Blue 1 (E133), FD&C Yellow 6 (E110) and yellow iron oxide [E172(iii)]. <p>The black printing ink contains shellac; Dehydrated alcohol; isopropyl alcohol; Butyl alcohol; Propylene glycol; purified water; strong ammonia solution; potassium hydroxide; and black iron oxide (E172).</p>
Potential allergens	Does contain Lactose

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

What Lenalide looks like

The capsules are provided in packs.

There are three (3) pack sizes available. A pack will contain either two blisters, each with seven capsules, giving a total of fourteen (14) capsules per pack or three blisters, each with seven capsules, giving a total of twenty-one (21) capsules per pack; or four blisters, each with seven capsules, giving a total of twenty-eight (28) capsules per pack. Some strengths and pack sizes of Lenalide may not be available as not all strengths and pack sizes are being distributed.

Lenalide 2.5 mg capsules are white/white printed with "NAT" on the cap and "2.5 mg" on the body of the capsules. (AUST R 338520)

Lenalide 5 mg capsules are white/white printed with "NAT" on the cap and "5 mg" on the body of the capsule (AUST R 338518).

Lenalide 7.5 mg capsules are white/white printed with "NAT" on the cap and "7.5 mg" on the body of the capsule (AUST R 338521).

Lenalide 10 mg capsules are white/white printed with "NAT" on the cap and "10 mg" on the body of the capsule (AUST R 338515).

Lenalide 15 mg capsules are white/white printed with "NAT" on the cap and "15 mg" on the body of the capsule. (AUST R 338526).

Lenalide 20 mg capsules are green/blue capsules with "20 mg" written on them. (AUST R 338522)

Lenalide 25 mg capsules are green/Blue printed with "NAT" on the cap and "20 mg" on the body of the capsule (AUST R 338527).

Who distributes Lenalide

Juno Pharmaceuticals Pty Ltd,
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Australia

www.junopharm.com.au

This leaflet was prepared in March 2025.