Lenalidomide-Teva®

Consumer Medicine Information (CMI) summary

The full CMI 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 Lenalidomide-Teva?

Lenalidomide-Teva contains the active ingredient lenalidomide (as lenalidomide hydrochloride monohydrate). Lenalidomide-Teva is used to treat patients with Multiple Myeloma. Lenalidomide-Teva 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. For more information, see Section 1. Why am I using Lenalidomide-Teva? in the full CMI.

2. What should I know before I use Lenalidomide-Teva?

Do not use if you have ever had an allergic reaction to Lenalidomide-Teva 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 Lenalidomide-Teva? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Lenalidomide-Teva 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 Lenalidomide-Teva?

- Your doctor will tell you how much Lenalidomide-Teva to take and for how long you will need to take it. More instructions can be found in Section 4. How do I use Lenalidomide-Teva? in the full CMI.

5. What should I know while using Lenalidomide-Teva?

Things you should do	• Remind any doctor, dentist or pharmacist you visit that you are using Lenalidomide-Teva. • **FEMALE PATIENTS:** Tell your doctor immediately if you become pregnant or suspect that you may be pregnant. You should also immediately stop taking Lenalidomide-Teva in this case
Things you should not do	• **FEMALE PATIENTS:** Do not become pregnant whilst taking Lenalidomide-Teva. Do not have sexual intercourse without using effective means of contraception described to you by your doctor • **MALE PATIENTS:** Do not donate sperm during treatment or treatment interruption, or for at least 1 week after stopping treatment. Do not have sexual intercourse without using effective means of contraception described to you by your doctor • **ALL PATIENTS:** Do not donate blood during treatment or treatment interruption, or for at least 1 week after stopping treatment
Driving or using machines	• Be careful driving or operating machinery until you know how Lenalidomide-Teva affects you
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 package until it is time to take them. Keep this medicine where children cannot reach it

For more information, see Section 5. What should I know while using Lenalidomide-Teva? in the full CMI.

6. Are there any side effects?

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Lenalidomide-Teva. Like all medicines, Lenalidomide-Teva can have side effects, although not everybody gets them. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects. 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: Lenalidomide-Teva (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 Lenalidomide-Teva is taken during pregnancy, it may cause birth defects or death to an unborn baby. Do not take Lenalidomide-Teva if you are pregnant or think that you are pregnant.

Lenalidomide-Teva®

Active ingredient(s): *lenalidomide*

Consumer Medicine Information (CMI)

This leaflet provides important information about using Lenalidomide-Teva. **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 Lenalidomide-Teva.**

Where to find information in this leaflet:

1. Why am I using Lenalidomide-Teva?

Lenalidomide-Teva contains the active ingredient lenalidomide.

Lenalidomide-Teva belongs to a group of medicines called immunomodulating agents that work by acting on the cells involved in the body's immune system. The immune system is part of the body's defence which helps to fight illness and infection.

Treatment of Multiple Myeloma

Lenalidomide-Teva is used treat patients with Multiple Myeloma.

Multiple myeloma (MM) is a cancer of the bone marrow.

Treatment of Myelodysplastic Syndromes

Lenalidomide-Teva 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.

This causes a lack of healthy blood cells in the body. There are different types of MDS.

Lenalidomide-Teva is approved to treat a type of MDS where part of chromosome 5 is missing. This type of MDS is known as deletion 5q MDS (or 5q minus). Patients with this type of MDS often have low red blood cell counts that require treatment with blood transfusions. It is hoped that the use of Lenalidomide-Teva will reduce the need for blood transfusions.

2. What should I know before I use Lenalidomide-Teva?

Warnings

Do not use Lenalidomide-Teva 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.

  Lenalidomide-Teva 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 Program - see section 4. How do I use Lenalidomide-Teva?

Check with your doctor if you:

- have any other medical conditions
- take any medicines for any other condition

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 Pregnancy Prevention Program

- Lenalidomide-Teva (lenalidomide) is structurally related to 'thalidomide', which is known to cause severe life-threatening human birth defects (deformed babies) and can cause death to an unborn baby if taken during pregnancy. If Lenalidomide-Teva is taken during pregnancy, it may cause birth defects or death to an unborn baby.
- To avoid exposure to unborn babies, Lenalidomide-Teva is available only under a special distribution program which 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 Lenalidomide-Teva.
- Some of the requirements of Pregnancy Prevention Program are outlined in the following sections. Your doctor will discuss all the details with you.

FOR WOMEN TAKING LENALIDOMIDE-TEVA

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.

If you are able to become pregnant:

- Your doctor will discuss the potential risk to unborn babies if Lenalidomide-Teva 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.
- You should start your Lenalidomide-Teva treatment 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 Lenalidomide-Teva treatment, during treatment and treatment interruption, and for at least 4 weeks after Lenalidomide-Teva 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 Lenalidomide-Teva 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 Lenalidomide-Teva is excreted in human milk. Therefore, you should discuss with your doctor whether to discontinue breast-feeding while you are receiving this medicine.

FOR MEN TAKING LENALIDOMIDE-TEVA

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 Lenalidomide-Teva treatment, during treatment interruption, and for at least 7 days 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 7 days after stopping treatment.

FOR ALL PATIENTS TAKING LENALIDOMIDE-TEVA

Discuss with your doctor if you have or have had 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 co-ordination or pain in your hands and feet)
- Thyroid problems
- Abnormal kidney function
- Liver problems e.g. liver infections
- Allergic reactions to thalidomide or lenalidomide.

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

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

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

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

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

Your doctor may adjust your dose of Lenalidomide-Teva 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.

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 MM 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 Lenalidomide-Teva treatment. Therefore, your doctor will carefully evaluate the benefit and risk when you are prescribed this medicine

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 Lenalidomide-Teva and affect how it works.

- 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 Lenalidomide-Teva.

4. How do I use Lenalidomide-Teva?

How much to take

Your doctor will tell you how much Lenalidomide-Teva to take and for how long you will need to take it.

For treatment of NDMM in combination with bortezomib and dexamethasone, the usual starting dose of Lenalidomide-Teva is 25 mg once daily. Your doctor will tell you if you

are to take Lenalidomide-Teva for 14 continuous days of a 21-Day cycle or for 21 continuous days of a 28-Day cycle. Your doctor will also tell you the duration and the quantity of the other medicines to be taken in combination with Lenalidomide-Teva. After the initial treatment of about 24 weeks, you may have a stem cell transplant or your doctor may ask you to take 25 mg of Lenalidomide-Teva once daily for 21 days of a 28-Day cycle continuously.

For the treatment of NDMM after a stem cell transplant, the usual starting dose is 10 mg once daily continuously (28 days of a 28-Day cycle).

For the treatment of MM in combination with dexamethasone (either NDMM in patients not eligible for stem cell transplantation or MM in patients whose disease has progressed after one therapy), the usual starting dose is 25 mg once a day for 21 days of a 28-Day cycle.

For the treatment of MDS, the recommended starting dose is 10 mg once a day for 21 days of a 28-Day cycle.

Your doctor will monitor your progress, and may adjust your dose of Lenalidomide-Teva or stop your treatment based on the results of your blood tests and on your general condition.

How to take it

Swallow the capsules whole, preferably with water, once a day as directed by your doctor.

Do not open, break or chew the capsules.

If powder from inside the capsules leaks out and contacts 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.

When to take Lenalidomide-Teva

Lenalidomide-Teva should be taken either one hour before or two hours after eating food.

How long to take Lenalidomide-Teva

Continue taking Lenalidomide-Teva as instructed by your doctor, until your doctor tells you to stop.

Your doctor will keep a close check on you to make sure you continue to benefit from Lenalidomide-Teva.

If you forget to take Lenalidomide-Teva

If it is less than 12 hours before your next dose, skip the dose you missed 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 Lenalidomide-Teva

If you think that you have used too much Lenalidomide-Teva, 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 Lenalidomide-Teva?

Things you must do

FEMALE PATIENTS:

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

ALL PATIENTS:

- **Tell any other doctors, dentists, and pharmacists who are treating you that you are taking Lenalidomide-Teva.**
- **If you are about to be started on any new medicine, remind your doctor, dentist or pharmacist that you are taking Lenalidomide-Teva.**
- **Keep all of your doctor's appointments so that your progress can be checked.**

Your doctor will do some blood tests regularly and will check your general condition to make sure the medicine is working and to prevent unwanted side effects.

Remind any doctor, dentist or pharmacist you visit that you are using Lenalidomide-Teva.

Things you must not do

FEMALE PATIENTS:

- **Do not become pregnant whilst taking Lenalidomide-Teva.**
- **Do not have sexual intercourse without using effective means of contraception described to you by your doctor.**

MALE PATIENTS:

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

  Lenalidomide-Teva can pass into human semen.
- **Do not have sexual intercourse without using effective means of contraception described to you by your doctor.**

ALL PATIENTS:

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

  In Australia, patients with some types of cancer are permanently excluded from donating blood.
- **Do not stop taking Lenalidomide-Teva (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 Lenalidomide-Teva affects you.

Lenalidomide-Teva may cause dizziness, tiredness or blurred vision 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

- **Keep your capsules in a cool dry place where the temperature stays below 25°C.**
- **Keep your capsules in the original package 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.

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.

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.

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.

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
• 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.	**Speak to your doctor if you have any of these less serious side effects and they worry you.**
• 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	

Serious side effects

Serious side effects	What to do
• **Heart palpitations or fast heart beat, chest pains, dizziness or fainting, shortness of breath, weakness, or reduced ability to exercise.** These could be symptoms of atrial fibrillation (irregular heart beat) or tachycardia (fast heart beat). • **Bleeding (including nose-bleeds) or bruising more easily than normal.** Lenalidomide-Teva 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-Teva. • **Tiredness, headaches, shortness of breath, dizziness and looking pale.** Lenalidomide-Teva 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.	**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.**

Serious side effects	What to do
• **Tender swollen lymph nodes, low-grade fever, pain, or rash.** This could be due to worsening of your tumour (for patients with MCL).	

Very serious side effects

Very serious side effects	What to do
• **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 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. • **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.** These could be symptoms of kidney disease. • **Abdominal pain, dark urine, fever, joint pain, loss of appetite, nausea and vomiting, yellowing of the skin and/or eyes.** 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.	**Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these very serious side effects.** **You may need urgent medical attention or hospitalisation**

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 Lenalidomide-Teva contains

Active ingredient (main ingredient)	Lenalidomide (as lenalidomide hydrochloride monohydrate)
Other ingredients (inactive ingredients)	colloidal anhydrous silica microcrystalline cellulose croscarmellose sodium purified talc The capsule shells contain gelatin, titanium dioxide , black ink, and the following colourants:

	2.5 mg, 10 mg and 20 mg (indigo carmine aluminium lake, and iron oxide yellow); 7.5 mg (iron oxide yellow); and 15 mg (indigo carmine aluminium lake. The black printing ink used on the capsules contains shellac, ethanol absolute, isopropyl alcohol, butan-1-ol, propylene glycol, purified water , strong ammonia solution, potassium hydroxide, and iron oxide black.

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

What Lenalidomide-Teva 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; 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 Lenalidomide-Teva may not be available as not all strengths and pack sizes are being distributed.

Lenalidomide-Teva 2.5 mg capsules: hard, non-transparent capsules with black mark 2.5 on white body and with green cap.

Lenalidomide-Teva 5 mg capsules: hard, non-transparent capsules with black mark 5 on white body and with white cap.

Lenalidomide-Teva 7.5 mg capsules: hard, non-transparent capsules with black mark 7.5 on white body and with ivory cap.

Lenalidomide-Teva 10 mg capsules: hard, non-transparent capsules with black mark 10 on ivory body and with green cap.

Lenalidomide-Teva 15 mg capsules: hard, non-transparent capsules with black mark 15 on white body and with blue cap.

Lenalidomide-Teva 20 mg capsules: hard, non-transparent capsules with black mark 20 on blue body and with green cap.

Lenalidomide-Teva 25 mg capsules: hard, non-transparent capsules with black mark 25 on white body and with white cap.

Australian Registration Number:

Lenalidomide-Teva 2.5 mg AUST R 340333

Lenalidomide-Teva 5 mg AUST R 340336

Lenalidomide-Teva 7.5 mg AUST R 340345

Lenalidomide-Teva 10 mg AUST R 340337

Lenalidomide-Teva 15 mg AUST R 340338

Lenalidomide-Teva 20 mg AUST R 340334

Lenalidomide-Teva 25 mg AUST R 340335

Who distributes Lenalidomide-Teva

Lenalidomide-Teva is supplied in Australia by:

Teva Pharma Australia Pty Ltd

Level 1, 37 Epping Road

Macquarie Park NSW 2113

Australia)

This leaflet was updated in August 2022