

LENALIDOMIDE VIATRIS



Lenalidomide capsules 2.5 mg, 5 mg, 7.5 mg, 10 mg, 15 mg, 20 mg, 25 mg

What is in this leaflet

Please read this leaflet carefully before you start taking Lenalidomide Viatriis.

This leaflet answers some common questions about Lenalidomide Viatriis.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking Lenalidomide Viatriis against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine. You may need to read it again.

What Lenalidomide Viatriis is used for

Lenalidomide Viatriis contains an active substance called lenalidomide. It 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

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

- Lenalidomide Viatriis is used to treat adult patients who have been diagnosed with newly diagnosed Multiple Myeloma (NDMM) and who

have undergone a stem cell transplant.

- Lenalidomide Viatriis is used in combination with another medicine called dexamethasone to treat adult NDMM patients who are not eligible for stem cell transplantation.
- Lenalidomide Viatriis is also used in combination with dexamethasone to treat adult MM patients whose disease has progressed after one therapy.

Treatment of Myelodysplastic Syndromes

Lenalidomide Viatriis 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 Viatriis 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 Viatriis will reduce the need for blood transfusions.

Your doctor may have prescribed this medicine for another reason.

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

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

This medicine is not addictive.

Before you take Lenalidomide Viatriis

When you must not take it

Do not take this medicine if you are pregnant, or think that you may be pregnant, or planning to become pregnant.

It may cause birth defects (deformed babies) or may affect your developing baby if you take it during pregnancy.

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 the Restricted Access Program – see section 'Before you start to take it').

Do not take Lenalidomide Viatriis if you have an allergy to:

- any medicine containing lenalidomide
- any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include: shortness of breath; wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body; rash, itching or hives on the skin.

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

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

Before you start to take it

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 Lenalidomide Viatrix.

Your doctor will have enrolled you in the Restricted Access Program to ensure that lenalidomide is used safely.

The Restricted Access Program

Lenalidomide, the active ingredient in the medicine, 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 this medicine is taken during pregnancy, it may cause birth defects or death to an unborn baby.

To avoid exposure to unborn babies, Lenalidomide Viatrix is available only under a special distribution program called the Restricted Access Program. This program is designed to ensure that Lenalidomide Viatrix 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 Viatrix.

Some of the requirements of the Restricted Access Program are outlined in the following sections. Your doctor will discuss all the details with you.

1. For women taking Lenalidomide Viatrix

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 Viatrix 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 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 Viatrix treatment, during treatment and treatment interruption, and for at least 4 weeks after your 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 ligation
- 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 Viatrix 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 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 Lenalidomide Viatrix

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 Viatrix 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 7 days after stopping treatment.

3. For all patients taking Lenalidomide Viatrix

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

- 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 Viatris.

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

In New Zealand, patients with certain cancers may be 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 Viatris.

Your doctor should ask you to have a blood test every week for the first 8 weeks of treatment, and at least every month after that. Your doctor may adjust your dose of Lenalidomide Viatris 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 Viatris treatment. Therefore, your doctor will carefully evaluate the benefit and risk when you are prescribed this medicine.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other

medicines or have recently taken any other medicines, including medicines that you buy without a prescription from your pharmacy, supermarket or health food shop.

You should also tell any health professional who is prescribing a new medication for you that you are taking Lenalidomide Viatris.

Some medicines and Lenalidomide Viatris may interfere with each other. 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.

You may need different amounts of your medicines, or you may need to take different medicines.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

How to take Lenalidomide Viatris

Follow all directions given to you by your doctor carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the box, ask your doctor or pharmacist for help.

How much to take

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

For the treatment of NDMM after a stem cell transplant, the usual starting dose is 10 mg once daily.

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 per day for 21 out of 28 days.

For the treatment of MDS, the recommended starting dose is 10 mg once per day for 21 out of 28 days.

Your doctor will monitor your progress and may adjust your dose of Lenalidomide Viatris 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 a full glass of 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 it

Take your medicine on an empty stomach, either 1 hour before food or 2 hours after eating food. Food can interfere with the absorption of this medicine.

How long to take it

Your doctor will tell you how long to continue taking your medicine.

Continue taking Lenalidomide Viatris at about the same time each day for 21 days in a row and then stop taking it for the next 7 days. Repeat taking Lenalidomide Viatris for 21 days and stopping for 7 days until your doctor tells you to stop.

If you forget to take it

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 to take your medicine, ask your pharmacist for some hints.

While you are taking Lenalidomide Viatrix

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 Viatrix in this case.

All patients:

Tell any other doctors, dentists, and pharmacists who are treating you that you are taking Lenalidomide Viatrix.

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

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.

Things you must not do

Female patients:

Do not become pregnant whilst taking Lenalidomide Viatrix.

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 7 days 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.

In New Zealand, patients with some types of cancer may be excluded from donating blood.

Do not stop taking Lenalidomide Viatrix (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 to treat any other complaints unless your doctor tells you to.

Things to be careful of

Be careful driving or operating machinery until you know how Lenalidomide Viatrix affects you.

This medicine 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.

In case of overdose

If you take] too much (overdose)

Immediately telephone your doctor or the National Poisons Centre (telephone 0800 POISON or 0800 764 766) or go to accident and emergency at your nearest hospital if you think that you or anyone else may have taken too much Lenalidomide Viatrix. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Lenalidomide Viatrix.

All medicines can have side effects, although not everybody gets them. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- Diarrhoea; constipation; feeling sick (also called nausea); vomiting; stomach pain; indigestion; dehydration; dry mouth; toothache; increase or decrease in weight; increase or decrease in appetite; loss of taste.
- Itchiness; rash; redness of the skin; dry skin; excessive sweating.
- Dizziness; fainting; headache; shaking or tremors; 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; fall.
- Swelling of hands, ankles or feet.

The above list includes the more common side effects of your medicine.

Tell your doctor immediately if you notice any of the following:

- **Bleeding (including nosebleeds) or bruising more easily than normal.**
Lenalidomide Viatris 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 this medicine.
- **Tiredness, headaches, shortness of breath, dizziness and looking pale.**
Revlimid can reduce the number of red blood cells that carry oxygen around the body.
- **Numbness, tingling, 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 diabetes.
- **Abnormal eye movements, convulsions, or irregular heart rhythms.**
These could be due to low levels of minerals such as potassium, calcium, magnesium or sodium.

The above list includes serious side effects that may require medical attention.

If any of the following happens, stop taking Lenalidomide Viatris and see a doctor immediately or go to Accident and Emergency at your nearest hospital:

- **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.
- **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.

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation.

Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

Other side effects not listed above may also occur in some people. Tell your doctor if you notice any other effects.

Some of these 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.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

After taking Lenalidomide Viatris

Storage

Keep your capsules in the pack until it is time to take them.

If you take the capsules out of the pack they may not keep well.

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

Do not store Lenalidomide Viatris or any other medicine in the bathroom or near a sink. Do not leave it on a

window sill or in the car.
Heat and dampness can destroy some medicines.

Keep it 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.

Disposal

If your doctor tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Product description

What it looks like

Lenalidomide Viatris 5 mg capsule: Size 2, white opaque cap and white opaque body, hard-shell gelatin capsule filled with white to off-white powder. The capsule is axially printed with "MYLAN" over "LL 5" in black ink on both cap and body.

Lenalidomide Viatris 10 mg capsule: Size 0, green opaque cap and light grey opaque body, hard-shell gelatin capsule filled with white to off-white powder. The capsule is axially printed with "MYLAN" over "LL 10" in black ink on both cap and body.

Lenalidomide Viatris 15 mg capsule: Size 0, white opaque cap and white opaque body, hard-shell gelatin capsule filled with white to off-white powder. The capsule is axially printed with "MYLAN" over "LL 15" in red ink on both cap and body.

Lenalidomide Viatris 15 mg capsule: Size 0, white opaque cap and white opaque body, hard-shell gelatin capsule filled with white to off-white powder. The capsule is axially printed with "MYLAN" over "LL 25" in black ink on both cap and body.

Ingredients

Active ingredient:

Lenalidomide Viatris 2.5 mg capsule contains 2.5 mg of lenalidomide as the active ingredient.

Lenalidomide Viatris 5 mg capsule contains 5 mg of lenalidomide as the active ingredient.

Lenalidomide Viatris 7.5 mg capsule contains 7.5 mg of lenalidomide as the active ingredient.

Lenalidomide Viatris 10 mg capsule contains 10 mg of lenalidomide as the active ingredient

Lenalidomide Viatris 15 mg capsule contains 15 mg of lenalidomide as the active ingredient.

Lenalidomide Viatris 20 mg capsule contains 20 mg of lenalidomide as the active ingredient.

Lenalidomide Viatris 25 mg capsule contains 25 mg of lenalidomide as the active ingredient.

Inactive ingredients:

Lenalidomide Viatris capsules also contain:

- Starch pregelatinised
- Cellulose, microcrystalline
- Croscarmellose sodium
- Silica, colloidal anhydrous
- Sodium stearyl fumarate.

The capsule shells contain:

- Gelatin
- Titanium dioxide (E171)
- Yellow iron oxide (E172) – 2.5 mg, 7.5 mg, 10 mg & 20 mg capsules only
- Black iron oxide (E172) – 7.5 mg & 10 mg capsules only
- FD & C Blue #2 / Indigo carmine (E132) – 2.5 mg, 10 mg & 20 mg capsules only.

The black printing ink used on the 2.5 mg, 5 mg, 7.5 mg, 10 mg and 25 mg capsule shells contains:

- Shellac (E904)
- Dehydrated alcohol (E1510)
- Isopropyl alcohol
- Butyl alcohol
- Propylene glycol (E1520)
- Ammonia solution, concentrated (E527)
- Black iron oxide (E172)
- Potassium hydroxide (E525)

- Purified water.

The red printing ink used on the 15 mg and 20 mg capsule shells contains:

- Shellac (E904)
- Red iron oxide (E172)
- Isopropyl alcohol
- N-butyl alcohol
- Propylene glycol (E1520)
- Ammonia solution, concentrated (E527)
- Simeticone.

Contains sulfites.

If you want to know more

Should you have any questions regarding this product, please contact your pharmacist or doctor.

Who supplies this medicine

Lenalidomide Viatris is supplied in New Zealand by:

Viatris Ltd
PO Box 11-183
Ellerslie
AUCKLAND
www.viatris.co.nz

Telephone: 0800 168 169

Date of Preparation

06 March 2024.
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