Please refer to the Consumer Medicine Information for further information. This may be accessed through the following URL or by scanning the QR code below:

https://www.medsafe.govt.nz/consumers/cmi/l/LenalidomideViatris.pdf

Lenalidomide Viatris (lenalidomide) 5 mg, 10 mg, 15 mg & 25 mg. Prescription Medicine. For the treatment of multiple myeloma (MM) & myelodysplastic syndromes (MDS) in adults. Do not take if you: are allergic to lenalidomide or to any excipients; pregnant; of childbearing potential and unable to meet the conditions of the Pregnancy Prevention Program. Medicines have benefits and risks. Possible side effects include diarrhoea, constipation, nausea, fatigue, back pain, anaemia, insomnia. Tell your doctor if you experience bleeding or bruising; tiredness, headaches, dizziness; numbness, tingling of extremities; blurred vision; irregular heart rhythms. Take strictly as directed. If symptoms persist or you have side effects, see your healthcare professional. Ask your doctor if Lenalidomide Viatris is right for you. For more information, view the Consumer Medicine Information at www.medsafe.govt.nz. Lenalidomide Viatris is fully funded medicine subject to Special Authority and meeting the eligibility criteria- doctor's fees and pharmacy charges will apply. Viatris Limited, Auckland.
LEN-2024-0005. TAPS NP21287.

Lenalidomide Viatris (lenalidomide)

Patient Booklet

This document contains important safety information about Lenalidomide Viatris (lenalidomide) and advice on risk minimisation.

This booklet was developed by Viatris Ltd as part of the Lenalidomide Viatris Risk Minimisation Plan.

VIATRIS

WARNING: Lenalidomide Viatris (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 Viatris is taken during pregnancy, it may cause birth defects or death to an unborn baby. Do not take Lenalidomide Viatris if you are pregnant, think that you are pregnant or are planning to become pregnant. Lenalidomide passes into men's semen. So there is a risk if you have unprotected sex with a woman who can become pregnant.

Reporting of suspected adverse events is important for the monitoring of the safety of all medicines.
Any adverse events which are experienced with Lenalidomide Viatris should be reported by healthcare professionals and/or patients to:
Centre for Adverse Reactions Monitoring (CARM)
via https://pophealth.my.site.com/carmreportnz/s/ and/or
Viatris Care program:
(email) admin@viatriscare.co.nz or (Free call): 0800 111 229

1. Summary

You have been given this booklet because your doctor has prescribed Lenalidomide Viatris for you.

What is Lenalidomide Viatris?

Lenalidomide Viatris contains the active ingredient lenalidomide.

Lenalidomide Viatris works by affecting the body's immune system, which is part of the body's defence that helps to fight illness and infection.
Lenalidomide Viatris is used to treat Multiple Myeloma, and Myelodysplastic Syndromes.
Lenalidomide Viatris works by acting on the body's immune system and directly attacking the cancer. It works in a number of different ways:

- By stopping the cancer cells developing
- By stopping blood vessels growing in the cancer
- By stimulating part of the immune system to attack the cancer cells

For more information, please review the full Consumer Medicines Information (CMI), available from your doctor or at
https://www.medsafe.govt.nz/consumers/cmi/l/LenalidomideViatris.pdf

You must be enrolled into the Viatris Care program to be prescribed Lenalidomide Viatris treatment.

Key features of the Viatris Care program

- Only prescribers registered with Viatris Care can prescribe this medicine
- Only pharmacists registered with Viatris Care can dispense this medicine
- Only patients who have been formally enrolled in Viatris Care can receive this medicine
- Patients must sign a Patient Consent and agree to fully comply with all requirements of the program

You must contact your doctor and/or care team urgently if you:

- Suspect that you or your partner is pregnant.
- Feel unwell or develop any of the following:

- Any fever, chills, sore throat, cough, mouth ulcers or any other symptoms of infection
- Any bleeding or bruising in the absence of injury
- Any chest pain, or leg pain or swelling
- Any shortness of breath
- Any other symptom that causes concern
- If you have any risk factors for developing thromboembolic events, e.g. smoking, high blood pressure, high cholesterol, a clotting disorder, a previous blood clot (in a vein or artery), you should tell your doctor.

It is also important to note that people taking Lenalidomide Viatris must not donate blood during treatment with Lenalidomide Viatris, during treatment interruptions, or for at least 1 week after stopping treatment.

WARNING: Lenalidomide Viatris (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 Viatris is taken during pregnancy, it may cause birth defects or death to an unborn baby. Do not take Lenalidomide Viatris if you are pregnant, think that you are pregnant or are planning to become pregnant. Lenalidomide passes into men's semen. So there is a risk if you have unprotected sex with a woman who can become pregnant.

2. Safety information for all patients

Potential side effects

Like all medicines, Lenalidomide Viatris can cause side effects, although not everybody gets them. Some are more common than others and some are more serious than others. These are not all the side effects that have been reported with Lenalidomide Viatris. Ask your doctor or pharmacist, and refer to the Consumer Medicine Information, if you would like more information.

Most of the side effects are minor and temporary. However, some side effects may need medical attention. The most important thing is to be aware of what to expect and what to report to your doctor.

It is important that you talk to your doctor if you have any side effects during Lenalidomide Viatris treatment.

Serious side effects and what to look out for:

Low white blood cells and platelets

One of the most common serious side effects of Lenalidomide Viatris is a reduction in the number of white blood cells (that fight infection) and platelets (blood cells which help the blood to clot). For this reason, your doctor will arrange for you to have regular blood tests. The frequency of blood tests may vary; your doctor and care team will provide detailed guidance on testing frequency. Lenalidomide Viatris may also cause blood clots in the veins and arteries (thromboembolic events).

Contact your doctor immediately if you experience any of the following:

- Any fever, chills, sore throat, cough, mouth ulcers or any other symptoms of infection
- Any bleeding or bruising in the absence of injury
- Any chest pain, or leg pain or swelling
- Any other symptom that causes concern
- If you have any risk factors for developing thromboembolic events, e.g. smoking, high blood pressure, high cholesterol, a clotting disorder, a previous blood clot (in a vein or artery), you should tell your doctor.

Blood clots in veins, arteries and in the lungs

Lenalidomide Viatris treatment may increase the risk of you developing blood clots in some veins and arteries (“thromboembolic events”) in the body. People with myeloma may already have a higher risk of blood clots. Symptoms of a blood clot can be leg pains, swelling and redness of the lower legs or arms. This may be due to blood clots in the veins of your leg (deep vein thrombosis). Sometimes the clots can travel in your bloodstream to your lungs producing symptoms of chest pain and breathlessness. Any chest pain spreading to the arms, neck, jaw, back or stomach, feeling sweaty and breathless (symptoms of “pulmonary embolism”), feeling sick or vomiting may be due to blood clots in the arteries (which may be symptoms of a heart attack or “myocardial infarction”). You may be prescribed treatment to help prevent blood clots from forming.

If you have any risk factors for developing thromboembolic events, e.g. smoking, high blood pressure, high cholesterol, a clotting disorder, a previous blood clot (in a vein or artery), you should tell your doctor.

Contact your doctor immediately if you experience any of the following:

- Chest pain or difficulty breathing
- Pain or swelling in your arms or legs
- Severe blisters and bleeding in the lips, eyes, mouth, nose and genitals
- Any other symptom that causes concern.

Some less serious side effects with Lenalidomide Viatris are:

- Diarrhoea
- Feeling sick (nausea)
- Constipation
- Decreased appetite
- Muscle cramps or weakness
- Tiredness
- Swelling of hands, ankles or feet (oedema)
- Rashes
- Blurred vision

Remember, almost all side effects are temporary and can be easily prevented or treated. If you experience any side effect that causes you concern, contact your doctor or hospital team.

Special monitoring

- Because Lenalidomide Viatris can cause a drop in white blood cell and platelet counts, you will have regular blood tests during treatment.
- Your doctor will also monitor how well your kidneys are working. You will have blood tests more frequently in the first few months when you start treatment.

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 treatment has to be stopped for any reason, your doctor will discuss other treatment options with you.

3.Information for women who are able to become pregnant

Lenalidomide Viatris is expected to be harmful to an unborn baby

- Lenalidomide Viatris has been shown to produce birth defects in animals and it is expected to have a similar effect in humans
- An unborn child would be likely to be harmed if exposed to Lenalidomide Viatris during pregnancy
- If you are pregnant, if you think you may be pregnant or if you are planning to become pregnant you must not take Lenalidomide Viatris
- Some women who are not having regular periods or who are approaching menopause may still be able to become pregnant
- Every woman who is able to become pregnant, even if they are not planning to, must follow the precautions detailed in this section, designed to prevent you from becoming pregnant, and to ensure you are not pregnant. By signing your Patient Consent form form you are agreeing to follow these precautions
- You should start your Lenalidomide Viatris treatment as soon as possible after having a negative pregnancy test result.

If for any reason you think you have become pregnant while you are taking Lenalidomide Viatris, or in the 4 weeks after stopping treatment, you must immediately stop taking Lenalidomide Viatris and contact your doctor and/or care team.

Before starting Lenalidomide Viatris treatment you should discuss with your doctor whether there is any possibility that you could become pregnant.

You must follow the pregnancy prevention advice presented in this section unless you fall into one of the following categories:

- You are at least 50 years old and it has been at least one year since your last period (if your periods have stopped because of cancer therapy, then there is still a chance you could become pregnant)
- Your womb has been removed (hysterectomy)
- Your fallopian tubes and both ovaries have been removed (bilateral salpingo oophorectomy)
- You have premature ovarian failure, confirmed by a specialist gynaecologist
- You have the XY genotype, Turner's syndrome or uterine agenesis

You may need an appointment and tests with a specialist in women's reproductive medicine to confirm that you are unable to become pregnant. Every woman who is able to become pregnant, even if they are not planning to, must follow the precautions detailed in this section.

Contraception to prevent pregnancy

If you are a woman who could become pregnant you must either:

- Use adequate contraception* starting 4 weeks before Lenalidomide Viatris treatment, during treatment, during any breaks in treatment and for 4 weeks after stopping treatment

or

- You will not engage in sexual activity with a male partner starting 4 weeks before Lenalidomide Viatris treatment, during treatment, during any breaks in treatment and for 4 weeks after stopping treatment. You will be asked to confirm this on a monthly basis, every treatment cycle.

*Not all types of contraception are suitable during Lenalidomide Viatris treatment. You and your partner should discuss with your doctor suitable forms of contraception that you both find acceptable. If necessary, your hospital team can refer you to a specialist for advice on contraception.

Pregnancy tests to ensure you are not pregnant

- If you are a woman who could become pregnant, you must have a pregnancy test to make sure you are not pregnant before you start Lenalidomide Viatris treatment
- You must also have a pregnancy test every 4 weeks during your treatment, to make sure you are not pregnant
- Your next prescription for Lenalidomide Viatris cannot be dispensed until it is confirmed that you are not pregnant
- Pregnancy tests must be overseen by a doctor or nurse looking after you
- If you have had surgery to stop you becoming pregnant (tubal sterilisation), you do not need to have pregnancy tests.

Your doctor and pharmacist must be registered with the Viatris Care program to prescribe and dispense Lenalidomide Viatris for you.

Your doctor will register your personal details with the Viatris Care program. Details of your prescription and confirmation of a negative pregnancy test with each prescription are also entered in the Viatris Care program.

These details will be viewed by your pharmacist who will also seek your verbal confirmation of a negative pregnancy test before dispensing Lenalidomide Viatris. The pharmacist will document that the medication has been dispensed to you.

You must ensure that you receive your Lenalidomide Viatris within 7 days of a negative pregnancy test, or you will need a new medically supervised pregnancy test & prescription to obtain a new supply.

4. Information for women who are not able to become pregnant

Lenalidomide Viatris is expected to be harmful to an unborn baby

- Lenalidomide Viatris has been shown to produce birth defects in animals and it is expected to have a similar effect in humans
- An unborn child would be likely to be harmed if exposed to Lenalidomide Viatris during pregnancy
- Before starting Lenalidomide Viatris treatment you should discuss with your doctor whether or not there is any possibility that you could become pregnant
- Some women who are not having regular periods or who are approaching the menopause may still be able to become pregnant
- You may need an appointment and tests with a specialist in women's reproductive medicine to confirm that you are unable to become pregnant
- Every woman who is able to become pregnant even if they are not planning to must follow the precautions detailed in the section 'Information for women who are able to become pregnant'.

You are considered to be a woman who is not able to become pregnant if you fall into one of the following categories:

- You are at least 50 years old and it has been at least one year since your last period (if your periods have stopped because of cancer therapy, then there is still a chance you could become pregnant)

- Your womb has been removed (hysterectomy)
- Your fallopian tubes and both ovaries have been removed (bi-lateral salpingo oophorectomy)
- You have premature ovarian failure, confirmed by a specialist gynaecologist
- You have the XY genotype, Turner's syndrome or uterine agenesis.

Your doctor and pharmacist must be registered with the Viatris Care program to prescribe and dispense Lenalidomide Viatris for you.

Your doctor will register your personal details with the Viatris Care program.Details of your prescription are also entered in the Viatris Care program.

These details will be viewed by your pharmacist before dispensing Lenalidomide Viatris. The pharmacist will document that the medication has been dispensed to you.

You must ensure that you receive your Lenalidomide Viatris within 28 days of it being first prescribed or you will need a new prescription.

5. Information for men

Lenalidomide Viatris is expected to be harmful to an unborn baby

- Lenalidomide Viatris has been shown to produce birth defects in animals and it is expected to have a similar effect in humans
- An unborn child would be likely to be harmed if exposed to Lenalidomide Viatris during pregnancy
- Lenalidomide Viatris passes into human semen
- You must use a condom every time you have sexual contact with a woman who is pregnant or able to become pregnant and who does not use effective contraception
- Even if you have had a vasectomy, you must use a condom throughout your Lenalidomide Viatris treatment, during any breaks in treatment and for at least 1 week after stopping treatment
- If your partner becomes pregnant while you are taking Lenalidomide Viatris, you must contact your doctor immediately, and your partner should also inform her doctor immediately
- You must not donate semen during treatment and for 1 week after stopping treatment.

Your doctor and pharmacist must be registered with the Viatris Care program to prescribe and dispense Lenalidomide Viatris for you.

Your doctor will register your personal details with the Viatris Care program. Details of your prescription are also entered in the Viatris Care program.

These details will be viewed by your pharmacist before dispensing Lenalidomide Viatris. The pharmacist will document that the medication has been dispensed to you.

You must ensure that you receive your Lenalidomide Viatris within 28 days of it being first prescribed, or you will need a new prescription.

6. What you should tell your doctor before taking Lenalidomide Viatris

- If you are pregnant, if you think you may be pregnant or if you are planning to become pregnant, as Lenalidomide Viatris may be harmful to an unborn child
- If you think you are able to become pregnant and need advice on effective contraception
- If you are breastfeeding
- If you have previously had an allergic (hypersensitive) reaction to thalidomide, lenalidomide or any other ingredients in Lenalidomide Viatris
- If you have or have had any of the following:
    - Thrombosis (blood clots), heart attack, high blood pressure or high cholesterol
    - Frequent bleeding or bruising
    - Frequent infections
    - Hepatitis B infection
    - Peripheral neuropathy (numbness, tingling, weakness, abnormal coordination or pain in your hands and feet)
    - Thyroid problems
    - Kidney problems
    - Liver problems
- If you are taking or have recently taken any other medicines, including medicines bought without a prescription.

7. How to take your medication

Please remember that your Lenalidomide Viatris must only be taken by you. Do not share your medicine with anyone else, even if they have similar symptoms to you.

Your pharmacist can give you help and advice on taking your medicines. Some people find it helpful to mark on a calendar when they have taken their medicines each day or to set an alarm clock to remind them to take their medicines.

Please review the full Consumer Medicines Information (CMI) provided by your doctor and available at https://www.medsafe.govt.nz/consumers/cmi/l/LenalidomideViatris.pdf before you take Lenalidomide Viatris.

The CMI provides important information about using Lenalidomide Viatris.

The following information can be found in the CMI:

1. Why am I taking Lenalidomide Viatris?
2. What should I know before I take Lenalidomide Viatris?
3. What if I am taking other medicines?
4. How do I take Lenalidomide Viatris?
5. What should I know while taking Lenalidomide Viatris?
6. Are there any side effects?
7. Medicine details

8. Patient informed consent

You will be asked to sign the Patient Consent Form after:

1. Your doctor has discussed with you all the details about your treatment with lenalidomide, especially the precautions regarding pregnancy
2. You have been provided a copy of this patient booklet
3. You have been provided a Patient Card. This card holds safety details for you and healthcare professionals regarding Lenalidomide Viatris and the Viatris Care program. Lenalidomide Viatris is expected to cause severe birth defects or death to an unborn baby & the program is designed to minimise this risk.
4. You have been provided with a copy of the Consumer Medicine Information (CMI)
5. You have read the information in the patient booklet and the CMI.

9. End of treatment requirements

After completing your Lenalidomide Viatris treatment, it is important that you:

- Return any unused Lenalidomide Viatris capsules to your pharmacist for safe disposal.
- Do not donate blood for at least 1 week.
- In New Zealand, patients with some cancers may be permanently excluded from donating blood.

Additional advice for women who are able to become pregnant:

- Continue using your effective pregnancy prevention method for a further 4 weeks
- Your doctor will perform a final pregnancy test after 4 weeks.

Additional advice for male patients:

- If you have been using an effective pregnancy prevention method, you must continue doing so for at least 1 week after stopping treatment.
- If your female partner has been using an effective pregnancy prevention method, she must continue doing so for at least 1 week.
- Do not donate semen or sperm for at least 1 week.

10. Additional information

What is multiple myeloma?

Myeloma is a type of cancer that affects plasma cells. Plasma cells are produced in the bone marrow and form part of the body's immune system. The function of the immune system is to fight disease and infection. Myeloma can occur in multiple parts of the bone marrow, which is why it is often called multiple myeloma. Multiple myeloma that does not respond to or returns after initial treatment is referred to as relapsed or refractory multiple myeloma.

What are Myelodysplastic syndromes (MDS)?

Myelodysplastic syndromes (MDS) are a collection of many different blood and bone marrow diseases. The blood cells become abnormal and do not function properly. Patients can experience a variety of signs and symptoms including a low red blood cell count (anaemia), the need for a blood transfusion, and an increased risk of infection.