Cipla

Lenalidomide

Pregnancy Prevention Programme

Patient Brochure

Australia

Approved by TGA: November 2022

Risk Management contact details:

For information and questions on the Risk Management of Cipla products, the Pregnancy Prevention Programme, pharmacy registrations, pregnancy reporting form and for adverse event, please contact Cipla:

Email: Lenalidomide.cipla@cipla.com;

This brochure helps patients to understand the key educational information and risks of Lenalidomide treatment.

'Cipla Lenalidomide aRMM Program':	**This brochure also provides you with information on:**
• Lenalidomide must never be used by women who are pregnant, as just one capsule is expected to cause severe birth defects. • Lenalidomide must never be used by women who are able to become pregnant unless they follow the Lenalidomide Pregnancy Prevention Programme • If lenalidomide is taken during pregnancy, it is expected to cause severe birth defects or death to an unborn baby. • Cipla has designed a pregnancy prevention programme (PPP) to make sure that unborn babies are not exposed to lenalidomide. It will provide you with information about what to expect from your treatment and explain the risks and your responsibilities. • Lenalidomide passes into men's semen and is expected to cause severe birth defects or death to an unborn baby. So, there is a risk if you have unprotected sex with a woman who can become pregnant.	• What to do before, during and after taking lenalidomide • Safety requirements for lenalidomide • Risk of donating blood/semen during treatment and for seven days after treatment • Safe handling of lenalidomide and the safe disposal of unused lenalidomide capsules • This brochure will help you understand what to do before, during and after taking lenalidomide. • This brochure will not give you information about multiple myeloma and follicular lymphoma. You should ask your prescriber if you have any questions

Preventing harm to unborn babies:

If lenalidomide is taken during pregnancy it is expected to cause severe birth defects or death to an unborn baby.

For complete information on all possible side effects, please read the Package Leaflet that comes with your lenalidomide capsules.

For your health and safety, please read this brochure carefully. Please ask your prescriber for further explanation if you do not understand something.

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Introduction

This medicine contains the active substance 'lenalidomide'. Lenalidomide is an immunomodulatory medicinal product that works by affecting the body's immune system and directly attacking cancer. It works in several different ways:

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

Lenalidomide is structurally related to thalidomide. Thalidomide is a known human teratogenic agent that causes severe life-threatening birth defects. Precautions must be taken to avoid exposure to lenalidomide in an unborn baby.

If lenalidomide is taken during pregnancy, a teratogenic effect is expected. Therefore, lenalidomide is contraindicated during pregnancy and in a female patient of childbearing potential unless all the conditions of the pregnancy prevention program are met.

Lenalidomide is used for multiple myeloma

Multiple myeloma
Multiple myeloma is a type of cancer that affects a certain kind of white blood cell called the plasma cell. These cells collect in the bone marrow and divide, becoming out of control. This can damage the bones and kidneys.

Multiple myeloma generally cannot be cured. However, the signs and symptoms can be greatly reduced or disappear for a period. This is called a 'response'.

- Newly diagnosed multiple myeloma – in patients who have had a bone marrow transplant
- Newly diagnosed multiple myeloma – in patients who cannot have a bone marrow transplant
- Multiple myeloma – in patients who have had treatment before

Lenalidomide is used for Myelodysplastic Syndromes (MDS)

- Lenalidomide is indicated for the treatment of patients with transfusion-dependent anaemia due to low- or intermediate-1 risk myelodysplastic syndromes associated with a deletion 5q cytogenetic abnormality with or without additional cytogenetic abnormalities.

- Lenalidomide is structurally related to thalidomide, which is known to cause severe, life-threatening birth defects.
- Precautions must be taken to avoid exposure to lenalidomide in an unborn baby-

This brochure contains important information about the Lenalidomide Pregnancy Prevention Programme.

You must read the information carefully, and before starting treatment, you should:

- Understand the risks of lenalidomide treatment. Please ensure you read the Package Leaflet before you use the medication, as it contains information on all the side effects that can occur with lenalidomide.
- Understand the guidelines for taking lenalidomide safely, including how to prevent pregnancy
- Understand what to expect during your initial and follow-up consultations with your prescriber
- Your prescriber will have explained to you the risks of lenalidomide treatment and specific instructions that you must follow
- Please make sure that you understand what your prescriber has told you before starting lenalidomide

If you don't understand something, please ask your prescriber for further explanation.

Lenalidomide and Birth Defects

All medicines can cause unwanted effects or 'side effects'. An extremely important side effect of lenalidomide is that if taken during pregnancy, it is expected to cause severe birth defects or death to an unborn baby. The birth defects include shortened arms or legs, malformed hands or feet, eye or ear defects, and internal organ problems. This means lenalidomide must never be taken by:

- Women who are pregnant
- Women who could become pregnant, even if you are not planning to become pregnant, unless they follow the Lenalidomide Pregnancy Prevention Programme

Lenalidomide and Other Possible Side Effects

Like all medicines, lenalidomide can cause side effects, although not everybody gets them. Some side effects are more common than others and some are more serious than others. Ask your prescriber or pharmacist if you would like more information or refer to the Package Leaflet. Most side effects are temporary and can be easily prevented and treated. The most important thing is to be aware of what to

expect and what to report to your prescriber. It is important that you talk to your prescriber if you have any side effects during lenalidomide treatment.

- **Report the event to the Therapeutic Goods Administration (TGA) via the Blue Card Scheme website: www.tga.gov.au/reporting-problems**
- **Alternatively, Blue Cards for reporting are available:**
  - by mail to Pharmacovigilance and Special Access Branch, Reply Paid 100, Woden ACT 2606;
  - by emailing adr.reports@tga.gov.au;
  - by FAX to 02 6232 8392;-

Pregnancy Prevention Programme (PPP)

The PPP includes the requirement for a controlled access program to minimise the risk of foetal exposure to lenalidomide.

- Tell your doctor if you are pregnant or think you may be pregnant, or if you are planning to become pregnant, **as lenalidomide is expected to be harmful to your unborn child.**

- If you are able to become pregnant, you must take all necessary precautions to avoid becoming pregnant and to ensure that you do not become pregnant during treatment. You should contact your doctor before starting treatment if you are able to become pregnant, even if you think this is unlikely.

- If you are able to become pregnant you must use an effective method of contraception for four weeks before starting treatment, during treatment and until four weeks after stopping treatment with lenalidomide (including dose interruptions), unless you abstain completely and permanently from sexual intercourse, this is confirmed on a monthly basis. If you are not using effective contraception, you should refer to a specialist for advice on contraception.

The following examples of appropriate methods of contraception may be considered:

  - Contraceptive implant;
  - Levonorgestrel Releasing Intra Uterine System (IUS)
  - Medroxyprogesterone acetate depot injection;
  - Tubal sterilisation;
  - Sex only with a man who has had a vasectomy that has been confirmed by two negative ejaculate tests;
  - Only progestogen-containing contraceptive pills (i.e. desogestrel) to inhibit ovulation.

- If you are able to become pregnant, and even if you agree and confirm that you do not have sex every month, you must have a pregnancy test under the supervision of a doctor before starting treatment. Tests will be repeated every four weeks during the treatment and for four weeks after the end of treatment, unless it is confirmed that you have had tubal sterilisation. Your doctor will

advise you which methods of contraception are appropriate as some methods of contraception are not recommended while taking lenalidomide. It is very important that you discuss this with your doctor.

- Contact your doctor for advice on proper contraception.
- If you think you are pregnant while taking lenalidomide or within four weeks after stopping it, you should immediately stop taking lenalidomide and inform your doctor. Your prescriber will refer you to a physician specialised or experienced in teratology for evaluation and advice.

Brochure for Women of Childbearing Potential

- **Lenalidomide is expected to be harmful to the unborn child.**
- **Lenalidomide has been shown to cause birth defects in animals and is likely to have similar effects in humans.**
- To ensure that lenalidomide does not harm your unborn baby, your doctor will complete a Treatment Initiation and Consent Form stating that you have been informed of the requirement for you **NOT** to become pregnant during treatment and for at least four weeks after stopping lenalidomide.
- Never share lenalidomide with anyone else.
- Always return any unused capsules to your pharmacist.
- Do not donate blood during treatment (including during dose interruptions) and for seven days after treatment finishes.
- For additional information, please refer to the Package Leaflet.
- You must never take lenalidomide if:
  - You are pregnant
  - You are a woman who is able to become pregnant, even if you are not planning to become pregnant, unless all of the conditions of the Pregnancy Prevention Programme are met.
- **If you experience any side effects when taking lenalidomide, talk to your doctor or pharmacist.**

Childbearing Potential Assessment

Female patients will be assessed by their prescriber for childbearing potential, and unless you fall into one of the following categories you must follow the contraceptive advice:

- 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 syndrome or uterine agenesis.

The following examples of appropriate methods of contraception may be considered:

- Contraceptive implant;
- Levonorgestrel Releasing Intra Uterine System (IUS)
- Medroxyprogesterone acetate depot injection;

- Tubal sterilisation;
- Sex only with a man who has had a vasectomy that has been confirmed by two negative ejaculate tests;
- Only progestogen-containing contraceptive pills (i.e. desogestrel) to inhibit ovulation.

Brochure for Women of Non-Childbearing Potential

- **Lenalidomide is expected to be harmful to the unborn baby.**
- **Lenalidomide has been shown to cause birth defects in animals and is likely to have similar effects in humans.**
- To ensure that lenalidomide does not harm your unborn baby, your doctor will complete a Treatment Initiation and Consent Form with the patient stating that you cannot become pregnant.
- Female patients will be assessed by their prescriber for childbearing potential, and unless you fall into one of the following categories you must follow the contraceptive advice presented in the section above:
  - 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 syndrome or uterine agenesis.
- Never share lenalidomide with anyone else.
- Always return any unused capsules to your pharmacist.
- Do not donate blood during treatment (including during dose interruptions) and for seven days after treatment.
- For additional information, please refer to the Package Leaflet.
- If you experience any side effects when taking lenalidomide, talk to your doctor or pharmacist.

Brochure for Male Patients

- **Lenalidomide is likely to be harmful to the unborn child.**
- **Lenalidomide has been shown to cause birth defects in animals and is likely to have similar effects in humans.**
- To ensure that lenalidomide does not harm your unborn baby, your doctor will complete a Treatment Initiation and Consent Form stating that you have been informed of the requirement for your partner **NOT** to become pregnant throughout the duration of your treatment with lenalidomide and at least for seven days after you stop taking lenalidomide.
- Never share lenalidomide with anyone else.
- Always return any unused capsules to your pharmacist.
- Do not donate blood or semen or sperm during treatment (including during dose interruptions) and for seven days after stopping treatment.
- Lenalidomide enters human sperm. If your partner is pregnant or could become pregnant and is not using effective contraception, you should use a condom during treatment, at intervals between doses, and at least for seven days after stopping treatment even if you had a vasectomy.
- If your partner becomes pregnant while you are taking lenalidomide or shortly after stopping treatment with lenalidomide, you should inform the doctor immediately, and it is recommended that your partner be referred to a doctor who specialises or has experience in teratology for evaluation and advice.
- For additional information, please refer to the Package Leaflet.
- If you experience any side effects when taking lenalidomide, talk to your doctor or pharmacist.

Brochure for ALL patients

Lenalidomide Treatment

Before Starting Your Treatment

Your prescriber will talk to you about what to expect from your treatment and explain the risks and your responsibilities.

If there is anything you do not understand, please ask your prescriber to explain it again.

Before starting treatment, your prescriber will ask you to read and sign a Treatment Initiation and Consent Form, which confirms that while taking lenalidomide:

• You understand the risks of birth defects and the actions you must take to prevent this risk from occurring depending on whether you are a female patient who can become pregnant, a male patient or a female patient who cannot become pregnant

• If you are able to become pregnant you will follow the necessary requirements to prevent pregnancy

• You understand the other important safety messages

• As a male patient, you understand the need to use condoms during treatment (including dose interruptions) and for at least seven days after stopping lenalidomide if your partner is pregnant or is of childbearing potential and not using effective contraception.

Your prescriber will keep one copy of your medical file and provide one copy to you.

Safety Measures During Treatment

There are additional measures you must understand while taking lenalidomide.

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

• Store your lenalidomide capsules safely, so no one else could take them by accident. Keep your lenalidomide capsules in the original box at room temperature

• Do not use after the expiry date written on the box. The expiry date refers to the last day of that month.

• Keep lenalidomide out of reach and sight of children.

Receiving Your Prescription

Your prescriber may provide you with a 'Prescription Authorisation Form' that must be provided to the pharmacist, which confirms that all of the 'Cipla Lenalidomide aRMM Programme' measures have been followed. Your pharmacist will ask to review this documentation prior to dispensing your lenalidomide.

For women of childbearing potential your prescriber will write a prescription for no more than four weeks supply, and you must have the medication dispensed within seven days of the prescription date.

For women of non-childbearing potential and male patients your prescriber will write a prescription for no more than 12 weeks supply.

You will need to see your prescriber each time you need a repeat prescription.

How to Take your Medication

Your pharmacist can provide you with help and advice on taking your medications. 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 medications.

• Your prescriber will prescribe a dose of lenalidomide suited to you

• Always take your medication exactly how your prescriber has told you. Check with your prescriber or pharmacist if you are not sure

• Your prescriber may adjust your dose depending on the result of blood tests and any side effects, you may experience

• Do not take more capsules than your doctor has prescribed. If in doubt, ask your prescriber or pharmacist for advice

• Lenalidomide capsules should be swallowed whole, with a glass of water

• Lenalidomide can be taken at any time of day, but it should be taken at approximately the same time each day

• Lenalidomide can be taken with or without food.

What to do if you have taken more than the prescribed dose of lenalidomide:

If you accidentally take too many capsules, contact your prescriber immediately.

What to do if you forget to take your lenalidomide:

If you forget to take your lenalidomide but remember within 12 hours of the missed dose you can take your lenalidomide as soon as you remember and continue with the next dose at the normal time. If it is more than 12 hours since the missed dose, leave out that dose altogether and take the next dose at the normal time.

Let your prescriber know if you have missed any doses at your next visit.

Taking other medicines

Please tell your prescriber or pharmacist if you are taking or have recently taken any other medicines, including medicines bought without a prescription. If you are seeing a different prescriber or other healthcare professionals for treatment (your dentist for example) you should tell them that you are taking lenalidomide and any other medications.

End of Treatment Requirements

After completing your lenalidomide treatment, it is important that:

• You return any unused lenalidomide capsules to your pharmacist

• You do not donate blood for at least seven days.

Additional advice for women of childbearing potential:

• Continue using your method of contraception method for at least a further four weeks

• Your prescriber will perform a final pregnancy test after at least four weeks, unless it is confirmed you have had a tubal sterilisation.

Additional advice for male patients:

• If you have been using an effective method of contraception, you must continue doing so for at least seven days

• If your female partner has been using an effective method of contraception, she must continue doing so for at least four weeks

• Do not donate semen or sperm for at least seven days.

Important advice on how to handle this medicine for patients, their families, and caregivers

Keep the capsules in the blister in the original package.

The capsules can sometimes be damaged when squeezing them out of the blisters, especially by squeezing them in the middle of the capsule. The capsules should not be squeezed out of the blisters by squeezing through the middle or both ends, as this may deform them and cause the capsules to break. It is recommended to press the end of the capsule only on one side (see figure), as the pressure will only be on one side, thus reducing the risk of deformation or breakage of the capsule. Healthcare professionals, caregivers and family members should wear disposable gloves when handling the blister or capsule. Gloves should then be removed carefully to prevent skin exposure, placed in a sealable plastic polyethylene bag and disposed of in accordance with local requirements. Hands should then be washed thoroughly with soap and water.
Women who are pregnant or suspect they may be pregnant should not handle the blister or capsule. Refer overleaf for further guidance.

If you are a family member and / or caregiver, use these precautions when handling this medicine to avoid possible exposure

- If you are a woman who is pregnant or suspect that you may be pregnant, you should not handle the blister or capsule
- Wear disposable gloves when handling the product and / or its packaging (e.g. blister or capsule).
- Take off the gloves in the right way to avoid possible skin contact (see below).
- Put on gloves in a sealed plastic polyethylene bag and dispose according to local requirements.
- Remove gloves, and wash hands thoroughly with soap and water.

If the package of the medicine is noticeably damaged, use these extra precautions to avoid exposure.

- If the outer box is noticeably damaged - **Do Not Open**.
- **Close outer carton Immediately.**
- If the blisters are damaged or leaking, or if you notice that the capsules are damaged or leaking,
- Place the product in a sealed plastic polyethylene bag.
- Return unused pack to your pharmacist as soon as possible for safe disposal.

If the product leaks or spills, take appropriate precautions to minimise exposure by using appropriate personal protection:

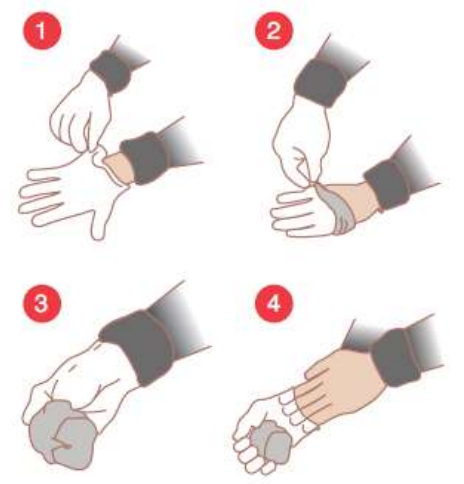
- If the capsules are crushed or broken, fine particles containing medicinal substance may be released. Avoid swallowing or inhaling the powder.
- Wear disposable gloves when cleaning the powder.
- Place a damp cloth or towel over the area where powder is released to allow less powder to enter the air. Add liquid to dissolve the substance. Thoroughly clean the area with soap and water and dry.
- Put all contaminated materials, including damp cloths or towels and gloves, in a sealed polyethylene plastic bag and dispose in accordance to local requirements for the disposal of medicinal products.
- Remove gloves, wash hands thoroughly with soap and water.
- Tell your doctor and / or pharmacist immediately.

If the contents of the capsules are adhered to the skin or mucous membranes

- If you touch the powder, wash the affected areas thoroughly under running water and soap.

- If the powder gets into your eyes and you do wear contact lenses, it is convenient to remove the contact lenses immediately and discard them. Immediately flush eyes with plenty of water for at least 15 minutes. If irritation develops, consult an ophthalmologist.

Proper glove removal method



- Grasp the outer side along the wrist (1).
- Take it off from hand by turning the inner part of the gloves outside (2).
- Hold the glove with the opposite gloved hand (3).
- Slide ungloved fingers under the wrist of the other glove. Be careful not to touch the outside of this glove (4).
- Squeeze from inside, forming a bag for both gloves.
- Discard it in the correct container.
- Wash your hands immediately with soap and water.

Check List

Please use this check list to confirm that you have understood all of the important information regarding your lenalidomide treatment.

All Patients

☐ Yes, I have received and understood all the information on the risks of birth defects associated with taking lenalidomide.

☐ Yes, I have received and understood all the information on the risks of other side effects associated with taking lenalidomide.

☐ Yes, I have understood that I must not donate blood during treatment (including dose interruptions), and for at least seven days after stopping treatment.

☐ Yes, I understand that I need to sign the Treatment Initiation Form before starting treatment.

Male Patients

☐ Yes, I have understood the need to use condoms during treatment, during dose interruption and for at least seven days after stopping lenalidomide, if I have a female partner who is pregnant or is able to get pregnant and not using effective contraception.

☐ Yes, I have understood I must not donate semen or sperm during treatment (including during dose interruptions) and for at least seven days after stopping lenalidomide.

Female Patients who can become pregnant

☐Yes, I will use one effective method of contraception for at least four weeks before starting lenalidomide, during therapy (even in the case of dose interruptions) and for at least four weeks after I have stopped lenalidomide treatment.

☐Yes, I understand that I need to have a negative pregnancy test result before starting to take my treatment, and for at least every four weeks during treatment and at least four weeks after stopping treatment (except in the case of confirmed tubal sterilisation).

The risk of neutropenia and thrombocytopenia and the need for regular blood tests

<u>Neutropenia: Management recommendations</u>

- Neutropenia may be managed with lenalidomide dose adjustments and/or administration of growth factors
- Complete blood counts, including white blood cell count with differential count, platelet count and haemoglobin, should be performed as follows:*
  - Transplant-ineligible ndMM patients: weekly for the first cycle, prior to the start of each new cycle and every 4 weeks thereafter when continued with dexamethasone
  - Transplant-eligible ndMM patients: weekly for the first cycle, prior to the start of each new cycle and every 4 weeks thereafter when continued with dexamethasone

* Patients with neutropenia should be monitored for signs of infection and patients should be advised to promptly report febrile episodes

Thrombocytopenia: Management recommendations

Thrombocytopenia may be managed by adjusting the dose of lenalidomide

- Complete blood counts, including white blood cell count with differential count, platelet count and haemoglobin, should be performed as follows:1
  - Transplant-ineligible ndMM patients: weekly for the first cycle, prior to the start of each new cycle and every 4 weeks thereafter when continued with dexamethasone
  - Transplant-eligible ndMM patients: weekly for the first cycle, prior to the start of each new cycle and every 4 weeks thereafter when continued with dexamethasone

The risk of venous and arterial thromboembolism and its management

In patients with multiple myeloma, the combination of lenalidomide/dexamethasone is associated with an increased risk of venous thromboembolism [VTE (predominantly DVT and PE)]. In patients with multiple myeloma or Myelodysplastic syndrome, treatment with lenalidomide monotherapy was associated with a lower risk of VTE (predominantly DVT and PE) than in MM patients treated with lenalidomide in combination therapy. In patients with multiple myeloma, the combination of lenalidomide/dexamethasone is associated with an increased risk of arterial thromboembolism [ATE (predominantly myocardial infarction and cerebrovascular event)]. The risk of ATE is lower in multiple myeloma patients treated with lenalidomide monotherapy than in multiple myeloma patients treated with lenalidomide in combination therapy

If a patient experiences any thromboembolic events, treatment must be discontinued and standard anticoagulation therapy started. Once the patient has been stabilised on the anticoagulation treatment and any complications of the thromboembolic event have been managed, the lenalidomide treatment may be restarted at the original dose dependent upon a benefit-risk assessment. The patient should continue anticoagulation therapy during the course of lenalidomide treatment.

Patients with known risk factors for thromboembolism (including prior thrombosis) should be closely monitored, and action should be taken to try to minimise all modifiable risk factors (e.g. smoking, hypertension, and hyperlipidaemia). Concomitant administration of erythropoietic agents or previous history of DVT may also increase thrombotic risk in these patients. Therefore, erythropoietic agents, or other agents that may increase the risk of thrombosis, such as hormone replacement therapy, should be used with caution in MM patients receiving lenalidomide/dexamethasone. A haemoglobin concentration above 120 g/L should lead to discontinuation of erythropoietic agents.

Patients and physicians are advised to be observant for the signs and symptoms of thromboembolism. Patients should be instructed to seek medical care if they develop symptoms such as shortness of breath, chest pain, arm or leg swelling. Prophylactic antithrombotic medicines, such as low molecular weight heparins or warfarin, should be recommended, especially in patients with additional thrombotic risk factors. The decision to take antithrombotic prophylactic measures should be made after careful assessment of an individual patient's underlying risk factors.

The risk of Ischaemic Heart Disease including Myocardial infarction

Myocardial infarction has been reported in patients receiving lenalidomide, particularly in those with known risk factors. Patients with known risk factors (including prior thrombosis) should be closely monitored, and action should be taken to try to minimise all modifiable risk factors (e.g. smoking, hypertension, and hyperlipidaemia).

Special monitoring

Because lenalidomide can cause a drop in white blood cell and platelet counts, you will have regular blood tests during treatment. Your prescriber 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 prescriber may adjust your dose of lenalidomide 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 prescriber will discuss other treatment options with you.

Remember, your pharmacist can give you help and advice on taking your medicines.

Reporting of Adverse Reactions

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

The safe use of lenalidomide is very important. As part of the safety monitoring Cipla wants to know about the side effects that have occurred with lenalidomide. If you get any side effects report to Cipla via Lenalidomide.cipla@cipla.com.

You can also report side effects directly via Blue Card Scheme at: www.tga.gov.au/reporting-problems

Alternatively, prepaid Blue Cards for reporting are available:

- by mail to Pharmacovigilance and Special Access Branch, Reply Paid 100, Woden ACT 2606 ;
- by emailing adr.reports@tga.gov.au;
- by FAX to 02 6232 8392;

Personal Notes

Please use this space to write down any questions for your prescriber for discussion at your next appointment.

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