

For the Patient: **MYLDREL**

Other Names: Treatment of Multiple Myeloma Using Lenalidomide (REVLIMID®) and Dexamethasone

MY = **MY**eloma (tumour group)
L = **L**enalidomide
D = **D**examethasone
REL = **REL**apse

Uses:

- **MYLDREL** is a drug treatment given for Multiple Myeloma.
- **MYLDREL** is currently offered to patients with myeloma that has progressed despite at least one prior treatment.

How does it work?

- **MYLDREL** is a combination of two drugs, lenalidomide (len a lid oh mide) and dexamethasone (dex a METH a sone). A third drug called cyclophosphamide (sy-cloh-foss-fa-mide) may be added to this treatment regimen for some patients.
- Lenalidomide is thought to directly kill myeloma cells, decrease myeloma cells attaching to the bone marrow, decrease the formation of blood vessels to the myeloma cells and increase the immune system to kill the myeloma cells.
- Dexamethasone (dex a METH a sone) works together with lenalidomide to directly kill myeloma cells.
- Cyclophosphamide prevents myeloma cells from dividing.

Intended Benefits:

- **MYLDREL** may stop or slow down the growth of myeloma cells in your body. This may improve your symptoms and delay or prevent new symptoms from developing.
- It will take between several weeks or months of treatment before your doctor can judge if the treatment is working.

Treatment Plan:

- It is a combination of two drugs (lenalidomide, dexamethasone) taken by mouth. If added, cyclophosphamide is also taken by mouth.
- Your treatment consists of cycles, each cycle is 28 days (day 1-28).

Lenalidomide

- You must be registered in a program called RevAid® to use lenalidomide. The RevAid® program was developed by Celgene (pharmaceutical company that makes lenalidomide) at the request of Health Canada to prevent lenalidomide from causing serious birth defects. Lenalidomide has a similar structure to the drug thalidomide.

- The RevAid® program will survey the patient and physician to make sure the following requirements are met:
 - birth control and pregnancy tests for women of child bearing potential
 - birth control for men who have sex with a woman of child bearing potential
 - that you will not donate blood or semen while taking lenalidomide and for four weeks following use
 - that you will not share lenalidomide
- Available in 25 mg, 20 mg, 15 mg, 10 mg, 5 mg and 2.5 mg capsules
- The RevAid® program will not allow a lenalidomide prescription that was filled at one pharmacy to be transferred to a different pharmacy to fill refills. This would require a new prescription from the doctor.
- The pharmacist must counsel you before each cycle can be dispensed. If another person is picking up your lenalidomide from the pharmacy for you, the pharmacist must counsel you over the phone before the drug can be dispensed.
- You, or the person picking up your lenalidomide for you, must wait for the pharmacist to complete the RevAid® dispensing steps.
- Lenalidomide is usually taken daily for 21 days, (days 1-21), followed by a 7 day rest (when no lenalidomide is taken), unless otherwise directed by your physician.
- Taken about the same time daily, best taken in the evening due to the fatigue side effect
- Swallow capsule whole, do not crush or break
- Can be taken with or without food
- Return unused drug to the pharmacy

Dexamethasone

- Usually given using 4 mg tablets
- Can be given in different dosing regimens as prescribed by your doctor
- Take as a single dose with food in the morning
- Some patients may not be able to take dexamethasone
- Other patients may take prednisone instead

Cyclophosphamide

- Usually given using 50 mg tablets
- May be taken **with food or on an empty stomach** with a glass of water
- **Avoid grapefruit and grapefruit juice** for 48 hours before and on the day of your cyclophosphamide dose as it may interact with cyclophosphamide
- Your doctor may ask you to **drink plenty of fluids** on the day of your cyclophosphamide dose and to empty your bladder (pass urine) frequently to prevent bladder and kidney problems

Labs:

- For the first 4 months, a blood test is done every 2 weeks
- Thereafter, blood tests are done every 4 weeks, about two days after stopping the lenalidomide.

- Your next cycle may be delayed, or your lenalidomide dose may be changed based on the blood test. Results are reviewed by the doctor and pharmacist before each cycle is dispensed
- Once you have your blood test done, if you have lenalidomide refills call the pharmacy, if you need a new prescription for lenalidomide call your physician

Serious Side Effects:

Unexpected and unlikely side effects can occur with any drug treatment. The ones listed below are particularly important as they are directly related to the common actions of these drugs.

- **Teratogenicity:** If lenalidomide is taken during pregnancy, it may cause severe birth defects or death to the fetus. Lenalidomide should never be used by women who are pregnant or who could become pregnant while taking the drug. Even a single dose taken by a pregnant woman may cause birth defects.
- **Infection:** You are at an increased risk for getting an infection if your white blood cells decrease. **If you have a fever over 38°C or 100°F, call your cancer doctor immediately (24 hours a day) or go immediately to your nearest Hospital Emergency and tell the doctor that you are on chemotherapy. It is recommended you have a working thermometer at home.**
- **Bleeding Problems:** You are at an increased risk of having bleeding problems if your platelets decrease. If you develop black tarry stools, blood in your urine, pinpoint red spots on the skin, or prolonged nose bleeds report them immediately to your doctor or nurse.
- **Blood Clots:** You are at an increased risk of forming a Deep Vein Thrombosis (DVT) or Pulmonary Embolism (PE). Your doctor may ask you to take **Aspirin 81 mg** daily or an anti-coagulant to prevent this. Signs of a blood clot include tenderness or hardness over a vein, calf tenderness, swelling – especially in one leg or arm but not the other, sudden onset of cough, chest pain or shortness of breath. **If you have signs of a blood clot call your cancer doctor immediately (24 hours a day) or go immediately to your nearest Hospital Emergency and tell the doctor that you are on chemotherapy.**

Common Side Effects and Management:

| SIDE EFFECTS | MANAGEMENT |
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| <p>Normal white blood cells protect your body by fighting bacteria (germs) that cause infection. When they are low, you are at greater risk of having an infection.</p> | <p>To help prevent infection:</p> <ul style="list-style-type: none"> • Wash your hands often and always after using the bathroom. • Avoid crowds and people who are sick. • Call your doctor <i>immediately</i> at the first sign of an infection such as fever (over 100°F or 38°C by an oral thermometer), chills, cough, or burning when you pass urine. |
| <p>Normal platelets help your blood to clot normally after an injury (e.g., cut). When the platelet count is low, you may be more likely to bruise or bleed.</p> | <p>To help prevent bleeding problems:</p> <ul style="list-style-type: none"> • Try not to bruise, cut, or burn yourself. • Clean your nose by blowing gently. Do not pick your nose. • Avoid constipation. • Brush your teeth gently with a soft toothbrush as your gums may bleed more easily. <p>Some medications such as ASA (e.g., ASPIRIN®) or ibuprofen (e.g., ADVIL®) may increase your risk of bleeding.</p> <ul style="list-style-type: none"> • Do not stop taking any medication that has been prescribed by your doctor (e.g., ASA for your heart). • For minor pain, try acetaminophen (e.g., TYLENOL®) first, but occasional use of ibuprofen may be acceptable. |
| <p>Blood clots may rarely occur. This is more likely to happen if you have had blood clots before. Signs to watch for include tenderness or hardness over a vein, calf tenderness, sudden onset of cough, chest pain, or shortness of breath.</p> | <p>To help prevent blood clots:</p> <ul style="list-style-type: none"> • Keep active. • Drink plenty of fluids. • Avoid tight clothing. <p>Do not sit with your legs crossed at the knees.</p> |
| <p>Fatigue is common. As the number of cycles increases fatigue may improve</p> | <ul style="list-style-type: none"> • Refer to the pamphlet '<i>Your Bank to Energy Savings-How people with cancer can handle fatigue</i>'.* • Take lenalidomide in the evening. • Sometimes a dose change may be required. |

| SIDE EFFECTS | MANAGEMENT |
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| <p>Skin rash and/or itching may sometimes occur, although in general it is not severe.</p> | <ul style="list-style-type: none"> • Minor rashes can be treated with diphenhydramine and/or steroid creams and lenalidomide can be continued. • Contact your doctor if rash worsens or is very irritating. |
| <p>Constipation may sometimes occur</p> | <ul style="list-style-type: none"> • Exercise if you can. • Drink plenty of fluids. • Try ideas in <i>Suggestions for Dealing with Constipation</i>.* |
| <p>Diarrhea may commonly occur</p> | <p>If diarrhea is a problem:</p> <ul style="list-style-type: none"> • Drink plenty of fluids. • Eat and drink often in small amounts. • Avoid high fibre foods as outlined in <i>Food Ideas to Help with Diarrhea During Chemotherapy</i>.* • Note: If lactose in milk usually gives you diarrhea, the lactose in the capsule may be causing your diarrhea. Take LACTAID® tablets just before your lenalidomide dose. |
| <p>Increased energy and difficulty sleeping may be due to dexamethasone</p> | <ul style="list-style-type: none"> • The days you take your dexamethasone you may feel as though you have extra energy. • You may also have difficulty sleeping at night. • Take the dexamethasone first thing in the morning to prevent difficulty sleeping at night. |

| SIDE EFFECTS | MANAGEMENT |
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| <p>Mouth sores may occur on the tongue, gums and sides of the mouth or in your throat from cyclophosphamide. Mouth sores or bleeding gums can lead to an infection.</p> | <ul style="list-style-type: none"> • Brush your teeth gently after eating and at bedtime with a very soft toothbrush. If your gums bleed, use gauze instead of a brush. Use baking soda instead of toothpaste. • Make a mouthwash with ¼ teaspoon baking soda AND ¼ teaspoon salt in 1 cup warm water and rinse several times a day • Try soft, bland foods like puddings, milkshakes and cream soups. • Avoid spicy, crunchy or acidic food, and very hot or cold foods. • Try the ideas in Food Ideas to Try with a Sore Mouth.* |

***Please ask your pharmacist for a copy.**

The pharmacists at BC Cancer and the pharmacists at your oncology clinic are also available to answer your drug-related questions.

Medication Interactions

Other drugs such as digoxin (LANOXIN®) may **interact** with lenalidomide. Tell your doctor if you are taking this or any other drugs as you may need extra blood tests or your dose may need to be changed. Check with your doctor or pharmacist before you start or stop taking any other drugs.

Some Natural Health Products may interact with this treatment. Tell your doctor if you are taking any Natural Health Products. Check with your doctor or pharmacist before you start taking any Natural Health Products.

If you experience symptoms or changes in your body that have not been described above but worry you, tell your doctor about them at the time of your next visit. If any symptoms are severe, contact:

_____ at telephone number _____

If you have symptoms that are severe or need emergency services, go to your local hospital's Emergency Department.