

For the Patient: UMYBLDF

Other Names: Treatment of Multiple Myeloma Using Bortezomib (Velcade[®]), Lenalidomide (REVLIMID[®]) and Dexamethasone

MY = MYeloma (tumour group)

B = Bortezomib

L = Lenalidomide

D = Dexamethasone

Uses:

- UMYBLDF is a drug treatment given for Multiple Myeloma.
- UMYBLDF is currently offered to patients with myeloma that have never received treatment before and will not be receiving stem cell transplant.

How does it work?

- UMYBLDF is a combination of three drugs, bortezomib (bor- TEZ-oh- mib), lenalidomide (len-a-lid-oh-mide) and dexamethasone (dex-a-METH-a-sona).
- Bortezomib is a drug that inhibits certain enzymes that play an important role in cell function and growth.
- 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 works together with lenalidomide to directly kill myeloma cells.

Intended Benefits:

- UMYBLDF 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 three drugs (bortezomib, lenalidomide and dexamethasone).
- Bortezomib is injected beneath the skin. Lenalidomide and dexamethasone are taken by mouth.
- Your treatment consists of cycles, each cycle is 28 days (day 1-28).
 - For cycles 1 - 8, you will receive injections every week for 3 out of 4 weeks (days 1, 8, and 15) and take medications by mouth
 - For cycles 9 and onwards, you will take medications by mouth only

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 doctor 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
- 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 doctor.
- 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 as 4 mg tablets (4 mg of dexamethasone per tablet)
- Can be given in different dosing regimens as prescribed by your doctor
- Take dexamethasone once a week as a single dose with food in the morning.
- Some patients may not be able to take dexamethasone
- Other patients may take prednisone instead

Labs:

- For the first 4 months, a blood test is done every 2 weeks
- Thereafter, blood tests are typically done every 4 weeks, within four days of your next chemotherapy cycle
- 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 doctor

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
<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>Pain or tenderness may occur where the needle was placed.</p>	<p>Apply cool compresses or soak in cool water for 15-20 minutes several times a day.</p>
<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>

SIDE EFFECTS	MANAGEMENT
<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. • Do not drive a car or operate machinery if you are feeling tired.
<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>Diarrhea may commonly occur with bortezomib and lenalidomide.</p>	<ul style="list-style-type: none"> • Diarrhea must be treated immediately with loperamide 2 mg tablets (e.g., IMODIUM®): • Take ONE tablet at the first sign of loose or more frequent stools than usual. • Then take ONE tablet every TWO hours until diarrhea has stopped for 12 hours • At night, you may take ONE tablet every FOUR hours (set your alarm) during the time you usually sleep. • Always keep a supply of loperamide (e.g., have 48 tablets on hand). You can buy loperamide at any pharmacy without a prescription. <p>To help diarrhea:</p> <ul style="list-style-type: none"> ▪ Drink plenty of liquids. ▪ Eat and drink often in small amounts. ▪ Avoid high fiber foods as outlined in Food Ideas to Help Manage Diarrhea. ▪ A dietitian can give you more suggestions for dealing with diarrhea <ul style="list-style-type: none"> • If diarrhea does not improve 24 hours after starting loperamide or lasts more than 36 hours, call your doctor.
<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>.*

SIDE EFFECTS	MANAGEMENT
Headache may sometimes occur.	<ul style="list-style-type: none"> • Take acetaminophen (e.g., TYLENOL®) every 4-6 hours if needed, to a maximum of 4 g (4000 mg) per day.
Muscle, joint, or back pain may sometimes occur.	<ul style="list-style-type: none"> • You may take acetaminophen (e.g., TYLENOL®) every 4-6 hours to a maximum of 4 g (4000 mg) per day for mild to moderate pain. Tell your doctor if the pain interferes with your activity.
Loss of appetite may sometimes occur.	<ul style="list-style-type: none"> • Try the ideas in Food Ideas to Help with Decreased Appetite
Increased energy and difficulty sleeping may be due to dexamethasone	<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.

***Please ask your pharmacist or chemotherapy nurse for a copy.**

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.

Other drugs and vitamin C supplements may interact with bortezomib. Green tea and preparations made from green tea should be avoided throughout the entire time that you are on bortezomib. These have been found to severely decrease the effectiveness of bortezomib, and might make it have no effect at all. Tell your doctor if you are taking any Natural Health Products. Check with your doctor or pharmacist before you start taking them.

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.