

## For the Patient: MYDARLD

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

**MY** = **MY**eloma (tumour group)

**DAR** = **DAR**atumumab

**L** = **L**enalidomide

**D** = **D**examethasone

### Uses:

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

### How does it work?

- **MYDARLD** is a combination of three drugs, daratumumab (dar a toom ue mab), lenalidomide (len a lid oh mide) and dexamethasone (dex a METH a sone).
- Daratumumab is a monoclonal antibody, a type of protein designed to target and interfere with the growth of cancer cells.
- 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:

- **MYDARLD** 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 (daratumumab, lenalidomide and dexamethasone).
- Daratumumab is a clear liquid that is either injected into a vein (given intravenously), or injected under the skin (given subcutaneously). Your treatment consists of cycles, each cycle is 28 days (day 1-28).
  - For cycles 1 and 2, you will receive treatment every week (days 1, 8, 15, 22)
  - For cycles 3 to 6, you will receive treatment every 2 weeks (days 1 and 15)
  - For cycles 7 onwards, you will receive treatment every 4 weeks (day 1 only)
- There are different options for administering the very first daratumumab dose. (The option will be determined by your doctor:

- Subcutaneous Option:
  - Premedications are given before daratumumab administration
  - daratumumab will be injected subcutaneously over 5 minutes into the abdomen. You will be in the treatment room for one hour after the injection is complete.
  - If it is tolerated, you will not need to stay after completion of injection for future doses of subcutaneous daratumumab
- Intravenous (IV) Options:
  - IV Option 1: Infuse daratumumab IV over 1 day
    - You will be in the treatment room for approximately 8 hours on the first day (day 1). Premedications are given before the daratumumab infusion and the IV infusion will take approximately 7 hours.
  - IV Option 2: Infuse daratumumab IV over 2 days
    - You will be in the treatment room for approximately 5 hours on each day. Premedications are given before the daratumumab infusion and the IV infusion will take approximately 4.5 hours
  - If it is tolerated, daratumumab will be infused IV at a faster rate and each cycle thereafter will take approximately 2 hours including premedication and observation post IV infusion.

**Lenalidomide:**

- You will take lenalidomide, an oral medication, daily for the first 21 days of each cycle (days 1 to 21) and dexamethasone (or prednisone) weekly. Pick up these medications from BC Cancer pharmacy the day before or at least 1 hour before your scheduled chemotherapy treatment.
- Within 4 days of each scheduled chemotherapy treatment, you will have a blood test and an appointment with the doctor to assess how you are tolerating your treatment.

**Daratumumab**

- May cause infusion reactions or administration-related reactions. Medications are given prior to the daratumumab treatment to prevent reactions. Please fill the prescription for montelukast and also buy acetaminophen 325 mg and either diphenhydramine 25 mg tablets or loratadine 10mg tablets, depending on which one your doctor orders . Pick up your dexamethasone from BC Cancer pharmacy the day before or *at least one hour before* your appointment as you will need to take these medications before the daratumumab treatment.
- During the daratumumab treatment, the nurse will monitor your heart rate, breathing and blood pressure. You will need to remain in the room for observation for 30 to 60 minutes after receiving the drug for the first 1 to 3 treatments, depending on the infusion or subcutaneous option. Your nurse will let you know when the observation time is complete.
- Redness, swelling, pain, or tenderness are possible with subcutaneous daratumumab treatment. These reactions typically occur within 1-2 days and usually disappear on their own. Apply cool compresses for 15-20 minutes

several times a day after the injection. Tell your healthcare team if these reactions are very painful or last longer than 2 days.

- During treatment with subcutaneous daratumumab, administer other subcutaneous drugs at alternative injection sites whenever possible

### **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
- The number of tablets you take will depend on the dose that your doctor prescribes for you.
- On the day of your daratumumab treatment, take your dexamethasone before the daratumumab.
- For cycle 1,
  - if you are receiving daratumumab subcutaneously, take your dexamethasone before daratumumab injection administration
  - if you are receiving daratumumab IV over 2 days, take dexamethasone 20mg before the infusion on **both** days

- if you are receiving daratumumab IV over 1 day, take your dexamethasone before the infusion on day 1
- On the weeks when you are not receiving daratumumab, take dexamethasone 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. <b>When they are low, you are at greater risk of having an infection.</b></p>	<p>To help prevent infection:</p> <ul style="list-style-type: none"> <li>• Wash your hands often and always after using the bathroom.</li> <li>• Avoid crowds and people who are sick.</li> <li>• Call your doctor <b><i>immediately</i></b> 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.</li> </ul>
<p>Normal platelets help your blood to clot normally after an injury (e.g., cut). <b>When the platelet count is low, you may be more likely to bruise or bleed.</b></p>	<p>To help prevent bleeding problems:</p> <ul style="list-style-type: none"> <li>• Try not to bruise, cut, or burn yourself.</li> <li>• Clean your nose by blowing gently. Do not pick your nose.</li> <li>• Avoid constipation.</li> <li>• Brush your teeth gently with a soft toothbrush as your gums may bleed more easily.</li> </ul> <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"> <li>• Do not stop taking any medication that has been prescribed by your doctor (e.g., <b>ASA for your heart</b>).</li> <li>• For minor pain, try acetaminophen (e.g., TYLENOL®) first, but occasional use of ibuprofen may be acceptable.</li> </ul>
<p><b>Allergic reactions</b> may sometimes occur. Signs of an allergic reaction may include runny or stuffy nose, throat irritation, cough, rash, itching, dizziness, and swelling or breathing problems including wheezing. This can occur immediately or several hours after receiving daratumumab.</p>	<p>Tell your nurse if this happens while you are receiving daratumumab or contact your oncologist immediately if this happens after you leave the clinic.</p>
<p><b>Pain or tenderness</b> 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>

SIDE EFFECTS	MANAGEMENT
<p><b>Fever</b> and <b>chills</b> may sometimes occur shortly after treatment with daratumumab. Fever should last no longer than 24 hours.</p>	<p>Take acetaminophen (e.g., <b>TYLENOL®</b>) every 4-6 hours, to a maximum of 4 g (4000 mg) per day. • Fever (over 100°F or 38°C by an oral thermometer) which occurs more than a few days after treatment may be a sign of an infection. Report this to your doctor immediately.</p>
<p><b>Blood clots</b> 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"> <li>• Keep active.</li> <li>• Drink plenty of fluids.</li> <li>• Avoid tight clothing.</li> </ul> <p>Do not sit with your legs crossed at the knees.</p>
<p><b>Fatigue</b> is common. As the number of cycles increases fatigue may improve</p>	<ul style="list-style-type: none"> <li>• Refer to the pamphlet '<i>Your Bank to Energy Savings-How people with cancer can handle fatigue</i>'.*</li> <li>• Take lenalidomide in the evening.</li> <li>• Sometimes a dose change may be required.</li> <li>• Do not drive a car or operate machinery if you are feeling tired.</li> </ul>
<p><b>Skin rash</b> and/or <b>itching</b> may sometimes occur, although in general it is not severe.</p>	<ul style="list-style-type: none"> <li>• Minor rashes can be treated with diphenhydramine and/or steroid creams and lenalidomide can be continued.</li> <li>• Contact your doctor if rash worsens or is very irritating.</li> </ul>
<p><b>Diarrhea</b> may commonly occur</p>	<p>If diarrhea is a problem:</p> <ul style="list-style-type: none"> <li>• Drink plenty of fluids.</li> <li>• Eat and drink often in small amounts.</li> <li>• Avoid high fibre foods as outlined in <i>Food Ideas to Help with Diarrhea During Chemotherapy</i>.*</li> <li>• <b>Note:</b> If lactose in milk usually gives you diarrhea, the lactose in the capsule may be causing your diarrhea. Take <b>LACTAID®</b> tablets just before your lenalidomide dose.</li> </ul>
<p><b>Constipation</b> may sometimes occur</p>	<ul style="list-style-type: none"> <li>• Exercise if you can.</li> <li>• Drink plenty of fluids.</li> <li>• Try ideas in <i>Suggestions for Dealing with Constipation</i>.*</li> </ul>

SIDE EFFECTS	MANAGEMENT
<b>Headache</b> may sometimes occur.	<ul style="list-style-type: none"> <li>• Take acetaminophen (e.g., TYLENOL®) every 4-6 hours if needed, to a maximum of 4 g (4000 mg) per day.</li> </ul>
<b>Muscle, joint, or back pain</b> may sometimes occur.	<ul style="list-style-type: none"> <li>• 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.</li> </ul>
<b>Loss of appetite</b> may sometimes occur.	<ul style="list-style-type: none"> <li>• Try the ideas in Food Ideas to Help with Decreased Appetite</li> </ul>
<b>Increased calcium</b> in the blood may sometimes occur.	To help prevent high calcium: <ul style="list-style-type: none"> <li>• Keep active.</li> <li>• Drink plenty of fluids</li> </ul>
<b>Increased energy and difficulty sleeping</b> may be due to dexamethasone	<ul style="list-style-type: none"> <li>• The days you take your dexamethasone you may feel as though you have extra energy.</li> <li>• You may also have difficulty sleeping at night.</li> <li>• Take the dexamethasone first thing in the morning to prevent difficulty sleeping at night.</li> </ul>

**\*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.

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 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.**