Daratumumab (Darzalex®)

Pronounced: dar-a-TOOM-ue-mab

Classification: monoclonal antibody

About Daratumumab (Darzalex®)

The immune system works by creating antibodies, which are proteins that attach to antigens found on the surface of a cell. The antibody “calls” the immune system to attack the cell it is attached to, resulting in the immune system killing the cell. Monoclonal antibodies are created in a lab to attach to the antigens found on specific types of cancer cells. These antibodies can work in different ways, including stimulating the immune system to kill the cell, blocking cell growth or other functions necessary for cell growth. Daratumumab is an antibody directed against a protein called CD38, which is found on the surface of multiple myeloma cells. Once daratumumab attaches itself to the cells expressing CD38, it summons the body’s immune system to attack and destroy those cells.

How to take Daratumumab

Daratumumab is given by intravenous infusion (IV, into a vein). The dose is dependent upon your size. The infusion time varies depending upon how many times you have received the infusion and how you tolerate each infusion. How often you receive this medication depends on what other medications you are receiving in your particular regimen.

Medications are given before and after the infusion to prevent reactions to the medicine. These medications include:

- IV corticosteroid (methylprednisolone) to prevent an infusion reaction.
- Acetaminophen (Tylenol) to prevent a fever.
- Oral or IV antihistamine (diphenhydramine/Benadryl) to prevent an infusion reaction.
- You will also receive an oral corticosteroid to take after treatment to reduce the risk of a delayed infusion reaction.
- For patients who have a history of obstructive pulmonary disorder (asthma, COPD), post-infusion medications may include short and long-acting bronchodilators and inhaled corticosteroids.
- Patients will also be instructed to take an antiviral medication to prevent herpes zoster reactivation. It should be started within 1 week of starting daratumumab and continue for 3 months after completion of treatment.

If you have a history of hepatitis B, you should tell your provider. This medication can cause the virus to reactivate.

Daratumumab can interfere with blood type testing (cross-matching and antibody screening). If you require a blood transfusion, be sure your provider and the blood bank know you have received this medication. A type and screen (blood test to check what type of blood you have) may be done prior to treatment with daratumumab.

Possible Side Effects of Daratumumab

There are a number of things you can do to manage the side effects of daratumumab. Talk to your care team about these recommendations. They can help you decide what will work best for you. These are some of the most common or important side effects:

Allergic Reactions

Some patients will experience some form of an allergic reaction to daratumumab, most commonly during the first infusion. Almost all reactions occurred during the infusion or within 4 hours of completion of the infusion. Signs of a reaction can include
cough, wheezing, throat tightness, swelling or irritation, nasal congestion, high or low blood pressure, high heart rate, dizziness, chest pain, headache, rash, itching, nausea, vomiting, and chills. If you notice any changes in how you feel during the infusion, let your nurse know immediately. The infusion will be stopped if this occurs and your side effects will be managed. If your side effects can be managed, the dose will continue to be administered, possibly at a slower rate.

Low White Blood Cell Count (Leukopenia or Neutropenia)

White blood cells (WBC) are important for fighting infection. While receiving treatment, your WBC count can drop, putting you at a higher risk of getting an infection. You should let your doctor or nurse know right away if you have a fever (temperature greater than 100.4°F/38°C), sore throat or cold, shortness of breath, cough, burning with urination, or a sore that doesn’t heal.

Tips to preventing infection:

- **Washing hands**, both yours and your visitors, is the best way to prevent the spread of infection.
- Avoid large crowds and people who are sick (i.e.: those who have a cold, fever or cough or live with someone with these symptoms).
- When working in your yard, wear protective clothing including long pants and gloves.
- Do not handle pet waste.
- Keep all cuts or scratches clean.
- Shower or bath daily and perform frequent **mouth care**.
- Do not cut cuticles or ingrown nails. You may wear nail polish, but not fake nails.
- Ask your oncology care team before scheduling dental appointments or procedures.
- Ask your oncology care team before you, or someone you live with has any vaccinations.

Low Platelet Count (Thrombocytopenia)

Platelets help your blood clot, so when the count is low you are at a higher risk of bleeding. Let your oncology care team know if you have any excess bruising or bleeding, including nose bleeds, bleeding gums or blood in your urine or stool. If the platelet count becomes too low, you may receive a transfusion of platelets.

- Do not use a razor (an electric razor is fine).
- Avoid contact sports and activities that can result in injury or bleeding.
- Do not take aspirin (salicylic acid), non-steroidal, anti-inflammatory medications (NSAIDs) such as Motrin/Advil (ibuprofen), Aleve (naproxen), Celebrex (celecoxib) etc. as these can all increase the risk of bleeding. Please consult with your healthcare team regarding use of these agents and all over the counter medications/supplements while on therapy.
- Do not floss or use toothpicks and use a soft-bristle toothbrush to brush your teeth.

Low Red Blood Cell Count (Anemia)

Your red blood cells are responsible for carrying oxygen to the tissues in your body. When the red cell count is low, you may feel tired or weak. You should let your oncology care team know if you experience any shortness of breath, difficulty breathing or pain in your chest. If the count gets too low, you may receive a blood transfusion.

Daratumumab can interfere with blood type testing (cross-matching and antibody screening). If you require a blood transfusion, be sure your provider and the blood bank know you have received this medication. This may affect the blood typing results for up to 6 months after the last daratumumab infusion. A type and screen (blood test to check what type of blood you have) may be done prior to treatment with daratumumab.

Diarrhea

Your oncology care team can recommend medications to relieve diarrhea. Also, try eating low-fiber, bland foods, such as white rice and boiled or baked chicken. Avoid raw fruits, vegetables, whole-grain breads, cereals, and seeds. Soluble fiber is found in some foods and absorbs fluid, which can help relieve diarrhea. Foods high in soluble fiber include applesauce, bananas (ripe), canned fruit, orange sections, boiled potatoes, white rice, products made with white flour, oatmeal, cream of rice, cream of wheat, and farina. Drink 8-10 glasses on non-alcoholic, un-caffeinated fluid a day to prevent dehydration.

Fatigue
Fatigue is very common during cancer treatment and is an overwhelming feeling of exhaustion that is not usually relieved by rest. While on cancer treatment, and for a period after, you may need to adjust your schedule to manage fatigue. Plan times to rest during the day and conserve energy for more important activities. Exercise can help combat fatigue; a simple daily walk with a friend can help. Talk to your healthcare team for helpful tips on dealing with this side effect.

**Nausea and/or Vomiting**

Talk to your oncology care team so they can prescribe medications to help you manage nausea and vomiting. In addition, dietary changes may help. Avoid things that may worsen the symptoms, such as heavy or greasy/fatty, spicy, or acidic foods (lemons, tomatoes, oranges). Try saltines, or ginger ale to lessen symptoms.

Call your oncology care team if you are unable to keep fluids down for more than 12 hours or if you feel lightheaded or dizzy at any time.

**Cold-Like Symptoms**

Some patients receiving daratumumab may experience cough and nasal congestion. These symptoms may be associated with an upper respiratory infection. If these symptoms become bothersome or you have a fever, notify your provider.

**Muscle or Joint Pain/Aches and Headache**

Your care team can recommend medications and other strategies to help relieve pain.

**Peripheral Edema**

Peripheral edema is swelling of the extremities caused by retention of fluid. It can cause swelling of the hands, arms, legs, ankles, and feet. The swelling can become uncomfortable. Notify your provider if you are experiencing any new or worsening swelling.

**Reproductive Concerns**

Exposure of an unborn child to this medication could cause birth defects, so you should not become pregnant or father a child while on this medication. Effective birth control is necessary during treatment and for at least 3 months after treatment. Even if your menstrual cycle stops or you believe you are not producing sperm, you could still be fertile and conceive. You should not breastfeed while receiving this medication.