Dinutuximab (Unituxin®)

**Pronounced:** din-ue-TUX-i-mab

**Classification:** Monoclonal Antibody

**About Dinutuximab (Unituxin®)**

Monoclonal antibodies are created in a lab to attach to the targets found on specific types of cancer cells. The antibody “calls” the immune system to attack the cell it is attached to, resulting in the immune system killing the cell. 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.

Dinutuximab is a monoclonal antibody that targets a substance found on certain cells, in this case it targets glycolipid GD2. It binds specifically to GD2, which is expressed on the surface of neuroblastoma tumor cells, as well as some normal cells. Dinutuximab binds to the GD2 and causes the cell to breakdown and die.

**How to Take Dinutuximab**

Dinutuximab is given as an intravenous infusion (into the vein). It may be given with other chemotherapy. The actual dose is based on the patient’s weight. Intravenous (IV) fluids will be administered prior to the infusion of dinutuximab. Pre-medications, including an antihistamine and an antipyretic (medication that prevents fever), will be given to prevent a reaction to the medication. Analgesics (pain relievers) will be administered prior to the start of the infusion, during the infusion and for two hours after it is complete.

**Possible Side Effects of Dinutuximab**

There are a number of things you can do to manage the side effects of dinutuximab. 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**

In some cases, patients can have an allergic reaction to this medication. Signs of a reaction can include: fever, facial or lip swelling, rash, difficulty breathing, lightheadedness, or dizziness within 24 hours following the infusion. If you notice any changes in how you feel during the infusion, let your nurse know immediately.

**Severe Pain and Peripheral Neuropathy (Numbness or Tingling in the Hands and/or Feet)**

Peripheral neuropathy is a toxicity that affects the nerves. It causes a numbness or tingling feeling in the hands and feet, often in the pattern of a stocking or glove. Dinutuximab can cause neuropathic pain during and after infusion. A patient will be given pain medications prior to the infusion, continuously throughout, and for two hours after the infusion is complete. This pain can get progressively worse with additional doses of the medication. In some people, the symptoms slowly resolve after the medication is stopped, but for some it never goes away completely. You should let your healthcare provider know if you experience numbness or tingling in the hands and feet, as they may need to adjust the doses of your medication.

**Capillary Leak Syndrome**

Capillary leak syndrome is a condition in which blood and components of blood leak out of vessels and into body cavities and muscles. The movement of this fluid out of the vessels can cause hypotension (low blood pressure) and organ failure. Signs and symptoms of capillary leak syndrome include: a sudden drop in blood pressure, weakness, fatigue, sudden swelling of the
arms, legs or other parts of the body, nausea, and lightheadedness. If you are having any of these symptoms notify your infusion nurse or provider immediately.

**Electrolyte Abnormalities**
Dinutuximab can cause abnormal electrolyte levels in your blood. You will have blood work drawn frequently to monitor these electrolytes and measures will be taken to correct abnormal levels. Some signs and symptoms of electrolyte abnormalities include seizures, heart palpitations, and muscle cramping. If you have any of these, contact your care provider immediately.

**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.

**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.

**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.

**Infection and Low White Blood Cell Count (Leukopenia or Neutropenia)**
This medication can cause life threatening infections, with or without a decrease in white blood cell counts.

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 or 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.

**Less common, but important side effects can include:**

- **Eye Concerns:** Dinutuximab can cause neurological disorders of the eye. The infusion will be interrupted with any vision changes, including dilated pupils or a sluggish reflex to light. The infusion will be discontinued if vision is lost. Notify your infusion nurse or care provider immediately with any changes to your vision.

- **Urinary Retention/Transverse Myelitis:** In rare cases this medication can cause the inability to urinate and inflammation of the spinal cord. Promptly report numbness, tingling, burning, weakness, or the inability to urinate to your care provider.

- **Atypical Hemolytic Uremic Syndrome:** Atypical Hemolytic Uremic Syndrome is a rare disease that affects kidney function and can cause kidney failure. Notify your care provider with any changes in your urine, including a change in the color of your urine, blood in the urine or a decrease in the amount of urine your are producing.

- **Posterior Reversible Encephalopathy Syndrome (PRES):** In rare cases this medication has caused a neurological disorder called posterior reversible encephalopathy syndrome (PRES), also called reversible posterior leukoencephalopathy (RPLS). Symptoms of PRES/RPLS include headache, seizure, lethargy, confusion, blindness and other visual and neurological disturbances. Report any of these symptoms to your healthcare team immediately.

**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. For women, effective birth control is necessary during treatment and for at least 2 months after treatment. Men should use condoms while being treated. Even if your menstrual cycle stops or you believe you are not producing sperm, you could still be fertile and conceive.