Naxitamab-gqgk (Danyelza®)

**Classification:** Monoclonal Antibody

**About Naxitamab-gqgk (Danyelza®)**

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.

Naxitamab-gqgk is a monoclonal antibody that targets a substance found on certain cells. This medication targets “glycolipid GD2.” It binds specifically to GD2, which is expressed on the surface of neuroblastoma tumor cells, as well as some normal cells. Naxitamab-gqgk binds to the GD2 and causes the cell to breakdown and die.

**How to Take Naxitamab-gqgk**

Naxitamab-gqgk is given as an intravenous infusion (IV, into a vein). The dose of naxitamab-gqgk is based on your weight. How long the infusion takes and how often you receive the medication will be determined by your team.

Before the infusion of naxitamab-gqgk, you will be given “pre-medications.” These may include medications to prevent or lessen any allergic reactions you may have. You may be given IV corticosteroids (like methylprednisone or dexamethasone), an antihistamine (like diphenhydramine), an H2 antagonist (like famotidine), an antipyretic to prevent fever (like acetaminophen), and an antiemetic to prevent nausea/vomiting. You may also be given medications to prevent and treat pain which you may continue to take after the infusion is done. This pain is nerve-related and medications can include gabapentin for neuropathic pain and opioid pain medications. You will be monitored for at least 2 hours after the infusion.

This medication is used with a medication called a granulocyte-macrophage colony-stimulating factor (GM-CSF), which will be given as an injection under your skin before and during your treatment cycle with Naxitamab-gqgk. A GM-CSF helps your body make more immune system cells, especially granulocytes and macrophages (white blood cells), which can attack and kill cancer cells. An example of a GM-CSF is sargramostim.

**Possible Side Effects of Naxitamab-gqgk**

There are a number of things you can do to manage the side effects of naxitamab-gqgk. Talk to your provider about these recommendations. They can help you decide what will work best for you. These are some of the most common side effects:

**Infusion and Allergic Reactions**

In some cases, patients can have an allergic reaction to this medication. Signs of a reaction can include: shortness of breath or difficulty breathing, coughing, chest pain, feeling like your heart is beating faster than normal, feeling faint, fever, chills, shakes, rash, flushing, itching, swelling of the lips or face, or a decrease in blood pressure. If you notice any changes in how you feel during the infusion, let your nurse know right away. The infusion will be slowed or stopped if this occurs. You will be given several medications before the infusion to help prevent these reactions.

**Neurotoxicity**

Neurotoxicity is an issue that affects the nerves and can cause nerve pain (neuropathic pain). Before receiving naxitamab-gqgk, your provider will prescribe medication to help prevent and treat neuropathic pain. You should let your healthcare provider know right away if you start to have:
- Numbness, pain, or tingling in the hands and feet.
- New or worse lower back pain.
- Pain in the neck or belly.
- Sharp, shooting feeling that goes down the legs, arms, or around your belly.
- Burning, coldness, loss of feeling in the legs.
- Trouble focusing or concentrating.
- Seizures.
- Change in vision.
- Headache.
- A hard time peeing.

**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 bread, 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.

**High Blood Pressure**

This medication can cause high blood pressure (hypertension). Patients should have their blood pressure checked regularly during therapy. Any hypertension should be treated appropriately. If hypertension cannot be controlled, the medication may be stopped. Report any headaches, vision changes or dizziness to your oncology care team.

**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 oncology care team if you are experiencing any new or worsening swelling.

**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.

**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 provider 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 for 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.

**Electrolyte Abnormalities**

This medication can affect the normal levels of electrolytes (potassium, magnesium, calcium, etc.) in your body. Your levels will be monitored using blood tests. If your levels become too low, your care team may prescribe specific electrolytes to be given by IV or taken by mouth. Do not take any supplements without first consulting with your care team.

**Changes to Blood Sugar Levels**

This medication can cause both higher and lower blood sugar levels in patients with and without diabetes. Your oncology care team will monitor your blood sugar. If you develop increased thirst, urination or hunger, blurry vision, headaches or your breath smells like fruit, notify your healthcare team. Diabetics should monitor their blood sugar closely and report any changes to the healthcare team.

**Liver Toxicity**

This medication can cause liver toxicity, which your oncology care team may monitor for using blood tests called liver function tests. Notify your healthcare provider if you notice yellowing of the skin or eyes, your urine appears dark or brown, or you have pain in your abdomen, as these can be signs of liver toxicity.

**Decrease in Appetite**

Nutrition is an important part of your care. Cancer treatment can affect your appetite and, in some cases, the side effects of treatment can make eating difficult. Ask your oncology care team about nutritional counseling services at your treatment center to help with food choices.

- Try to eat five or six small meals or snacks throughout the day, instead of 3 larger meals.
- If you are not eating enough, nutritional supplements may help.
- You may experience a metallic taste or find that food has no taste at all. You may dislike foods or beverages that you liked before receiving cancer treatment. These symptoms can last for several months or longer after treatment ends.
- Avoid any food that you think smells or tastes bad. If red meat is a problem, eat chicken, turkey, eggs, dairy products and fish without a strong smell. Sometimes cold food has less of an odor.
- Add extra flavor to meat or fish by marinating it in sweet juices, sweet and sour sauce or dressings. Use seasonings like
basil, oregano or rosemary to add flavor. Bacon, ham and onion can add flavor to vegetables.

**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 2 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 and for 2 months after treatment.

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