

Naxitamab-gqgk (Danyelza)

About This Drug

Naxitamab-gqgk is used to treat cancer. It is given in the vein (IV).

Possible Side Effects

- Bone marrow suppression. This is a decrease in the number of white blood cells, red blood cells, and platelets. This may raise your risk of infection, make you tired and weak, and raise your risk of bleeding.
- Increased heart rate
- Nausea and vomiting (throwing up)
- Diarrhea (loose bowel movements)
- Tiredness
- Fever
- Swelling of the hands, feet, or any other part of the body
- While you are getting this drug in your vein (IV), you may have a reaction to the drug. Sometimes you may be given medication to stop or lessen these side effects. Your nurse will check you closely for these signs: fever or shaking chills, flushing, facial swelling, feeling dizzy, headache, trouble breathing, rash, itching, chest tightness, or chest pain. These reactions may happen after your infusion. **If this happens, call 911 for emergency care.**
- Injection site reaction - you may get a rash, swelling or bruising or your skin may get red, warm, itchy, or painful at the site of your infusion.
- Decreased appetite (decreased hunger)
- Changes in your liver function
- Electrolyte changes
- Blood sugar levels may change
- Decrease in a blood protein called albumin
- Effects on the nerves called peripheral neuropathy. You may feel numbness, tingling, or pain in your hands and feet. It may be hard for you to button your clothes, open jars, or walk as usual. The effect on the nerves may get worse with more doses of the drug. These effects get better in some people after the drug is stopped but it does not get better in all people.
- Headache
- Pain
- Feeling nervous or worried (anxiety)
- Feeling irritable
- Cough

- Rash
- Itching
- High blood pressure

Note: Each of the side effects above was reported in 25% or greater of patients treated with naxitamab-gqgk. Not all possible side effects are included above.

Warnings and Precautions

- Severe peripheral neuropathy and other general effects on the nerves such as difficulty emptying your bladder, blurred vision, unequal pupil size, trouble focusing your eyes, and sensitivity to light (photosensitivity). Photosensitivity means that you may become more sensitive to the sun and/or light. Your eyes may water more, mostly in bright light.
- Severe nerve pain, including pain in your abdomen, bone, neck, legs, or arms.
- Swelling in the brain that is usually reversible. Symptoms can be sudden (acute) and may include a headache, confusion, changes in eyesight, extreme tiredness/coma, and/or seizures. **If you start to have any of these symptoms let your doctor know right away.**
- Severe infusion-related reactions
- Severely high blood pressure

Note: Some of the side effects above are very rare. If you have concerns and/or questions, please discuss them with your medical team.

Important Information

- This drug may be present in the saliva, tears, sweat, urine, stool, vomit, semen, and vaginal secretions. Talk to your doctor and/or your nurse about the necessary precautions to take during this time.

Treating Side Effects

- Manage tiredness by pacing your activities for the day.
- Be sure to include periods of rest between energy-draining activities.
- To decrease the risk of infection, wash your hands regularly.
- Avoid close contact with people who have a cold, the flu, or other infections.
- Take your temperature as your doctor or nurse tells you, and whenever you feel like you may have a fever.
- To help decrease the risk of bleeding, use a soft toothbrush. Check with your nurse before using dental floss.
- Be very careful when using knives or tools.
- Use an electric shaver instead of a razor.
- Drink plenty of fluids (a minimum of eight glasses per day is recommended).



- If you throw up or have diarrhea, you should drink more fluids so that you do not become dehydrated (lack of water in the body from losing too much fluid).
- To help with nausea and vomiting, eat small, frequent meals instead of three large meals a day. Choose foods and drinks that are at room temperature. Ask your nurse or doctor about other helpful tips and medicine that is available to help stop or lessen these symptoms.
- If you have diarrhea, eat low-fiber foods that are high in protein and calories and avoid foods that can irritate your digestive tracts or lead to cramping.
- Ask your nurse or doctor about medicine that can lessen or stop your diarrhea.
- To help with decreased appetite, eat small, frequent meals. Eat foods high in calories and protein, such as meat, poultry, fish, dry beans, tofu, eggs, nuts, milk, yogurt, cheese, ice cream, pudding, and nutritional supplements.
- Consider using sauces and spices to increase taste. Daily exercise, with your doctor's approval, may increase your appetite.
- Infusion reactions may occur after your infusion. **If this happens, call 911 for emergency care.**
- While you are getting this drug, please tell your nurse right away if you get a rash, swelling or bruising or your skin gets red, warm, itchy, or painful at the site of your infusion.
- Keeping your pain under control is important to your well-being. Please tell your doctor or nurse if you are experiencing pain.
- If you get a rash do not put anything on it unless your doctor or nurse says you may. Keep the area around the rash clean and dry. Ask your doctor for medicine if your rash bothers you.
- If you have numbness and tingling in your hands and feet, be careful when cooking, walking, and handling sharp objects and hot liquids.
- Wear dark sunglasses when in the sun or bright lights.
- If you have diabetes, keep good control of your blood sugar level. Tell your nurse or your doctor if your glucose levels are higher or lower than normal.

Food and Drug Interactions

- There are no known interactions of naxitamab-gqgk with food.
- This drug may interact with other medicines. Tell your doctor and pharmacist about all the prescription and over-the-counter medicines and dietary supplements (vitamins, minerals, herbs, and others) that you are taking at this time. Also, check with your doctor or pharmacist before starting any new prescription or over-the-counter medicines, or dietary supplements to make sure that there are no interactions.

When to Call the Doctor

Call your doctor or nurse if you have any of these symptoms and/or any new or unusual symptoms:

- Fever of 100.4° F (38° C) or higher
- Chills
- Tiredness or weakness that interferes with your daily activities
- Feeling dizzy or lightheaded
- Easy bleeding or bruising



- A headache that does not go away
- Blurred vision or any other changes in eyesight
- Unequal or large pupil size
- Sensitivity to light
- Confusion
- Extreme tiredness and/or coma
- Symptoms of a seizure such as confusion, blacking out, passing out, loss of hearing or vision, blurred vision, unusual smells or tastes (such as burning rubber), trouble talking, tremors or shaking in parts or all of the body, repeated body movements, tense muscles that do not relax, and loss of control of urine and bowels. **If you or your family member suspects you are having a seizure, call 911 right away.**
- Trouble understanding or speaking
- Trouble urinating and/or pain in your lower abdomen
- Numbness or lack of strength to your arms, legs, face, or body
- Feeling that your heart is beating fast or in a not normal way (palpitations)
- Cough that is bothersome
- Wheezing and/or trouble breathing
- Nausea that stops you from eating or drinking and/or is not relieved by prescribed medicines
- Throwing up more than 3 times a day
- Diarrhea, 4 times in one day or diarrhea with lack of strength or a feeling of being dizzy
- Lasting loss of appetite or rapid weight loss of five pounds in a week
- Weight gain of 5 pounds in one week (fluid retention)
- Swelling of the hands, feet, or any other part of the body
- Signs of infusion reaction: fever or shaking chills, flushing, facial swelling, feeling dizzy, headache, trouble breathing, rash, itching, chest tightness, or chest pain. **If this happens, call 911 for emergency care.**
- Signs of possible liver problems: dark urine, pale bowel movements, pain in your abdomen, feeling very tired and weak, unusual itching, or yellowing of the eyes or skin
- Pain that does not go away or is not relieved by prescribed medicine
- Numbness, tingling, or pain in your hands and feet
- New rash and/or itching
- Rash that is not relieved by prescribed medicines
- Abnormal blood sugar
- Signs of low blood sugar: feeling sleepy, increased hunger, sweating, shakiness, irritability
- If you think you may be pregnant

Reproduction Warnings

- **Pregnancy warning:** This drug may have harmful effects on the unborn baby. Women of childbearing potential should use effective methods of birth control during your cancer treatment and for 2 months after treatment. Let your doctor know right away if you think you may be pregnant.
- **Breastfeeding warning:** It is not known if this drug passes into breast milk. For this reason, women should not breastfeed during treatment and for 2 months after treatment because this drug could enter the breast milk and cause harm to a breastfeeding baby.



- **Fertility warning:** Fertility studies have not been done with this drug. Talk with your doctor or nurse if you plan to have children. Ask for information on sperm or egg banking.

Revised December 2021

