



**DANYELZA™**  
(naxitamab-gqqk)  
40mg/10mL Injection

## How to order DANYELZA® Under the medical benefit

DANYELZA is indicated, in combination with granulocyte-macrophage colony-stimulating factor (GM-CSF), for the treatment of pediatric patients 1 year of age and older and adult patients with relapsed or refractory high-risk neuroblastoma in the bone or bone marrow who have demonstrated a partial response, minor response, or stable disease to prior therapy.

This indication is approved under accelerated approval based on overall response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s).

### Y-mAbs Connect™

A program for health care professionals and patients that provides answers to questions related to access, insurance, financial support programs and other resource programs for qualifying patients. Your patient will be assigned a unique ID from Y-mAbs Connect for each individual order. You will use this patient-unique ID to place an order with a participating specialty distributor.

### Steps to getting your patient started on DANYELZA:

- 1 Prescriber enrolls patient in Y-mAbs Connect**
  - Visit [ymabsconnect.com](http://ymabsconnect.com) to download the Y-mAbs Connect enrollment form
  - Submit a completed enrollment form to Y-mAbs Connect
  - Verify patient's coverage for DANYELZA\*
  - Receive a patient-unique ID from Y-mAbs Connect
- 2 Place an order for DANYELZA through a participating specialty distributor using the patient-unique ID from Y-mAbs Connect**
- 3 Receive the DANYELZA shipment at the infusion site from a participating specialty distributor**

\*Y-mAbs Connect case managers could provide insurance verification support.

If a patient is already enrolled in Y-mAbs Connect, you can call 1-833-33Y-MABS (1-833-339-6227), option (2), Monday through Friday, 8AM to 8PM ET, to receive the patient-unique ID.

10-digit NDC	Description
73042-201-01	Carton containing one 40 mg/10 mL (4 mg/mL) single-dose vial

NDC=National Drug Code.

## IMPORTANT SAFETY INFORMATION

### WARNING: SERIOUS INFUSION-RELATED REACTIONS and NEUROTOXICITY

#### Serious Infusion-Related Reactions

- DANYELZA can cause serious infusion reactions, including cardiac arrest, anaphylaxis, hypotension, bronchospasm, and stridor. Infusion reactions of any Grade occurred in 94-100% of patients. Severe infusion reactions occurred in 32-68% and serious infusion reactions occurred in 4 - 18% of patients in DANYELZA clinical studies.
- Premedicate prior to each DANYELZA infusion as recommended and monitor patients for at least 2 hours following completion of each infusion. Reduce the rate, interrupt infusion, or permanently discontinue DANYELZA based on severity.

#### Neurotoxicity

- DANYELZA can cause severe neurotoxicity, including severe neuropathic pain, transverse myelitis and reversible posterior leukoencephalopathy syndrome (RPLS). Pain of any Grade occurred in 94-100% of patients in DANYELZA clinical studies.
- Premedicate to treat neuropathic pain as recommended. Permanently discontinue DANYELZA based on the adverse reaction and severity.

Please see additional Important Safety Information for DANYELZA on the following page, and the accompanying full Prescribing Information and Patient Information for DANYELZA including Boxed Warning on serious infusion-related reactions and neurotoxicity. The Prescribing Information is also available at [labeling.ymabs.com/danyelza](http://labeling.ymabs.com/danyelza)



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**Order through one of these participating specialty distributors:**

ASD Healthcare	Cardinal Health	McKesson Plasma & Biologics
1-800-746-6273 (p) 1-800-547-9413 (f)	1-866-681-3261 (p)	1-877-625-2566 (p) 1-888-752-7626 (f)
asd.customerservice@asdhealthcare.com	gmb-spd-mfgservicessp@cardinalhealth.com	mpborders@mckesson.com
asdhealthcare.com	N/A	N/A

If a DANYELZA® (naxitamab-gqgk) 40 mg/10 mL Injection order has previously been placed for a patient, you can call Y-mAbs Connect or the participating specialty distributor to receive the patient-unique ID again.

**How DANYELZA is supplied:**

DANYELZA injection is a sterile, preservative-free, clear to slightly opalescent and colorless to slightly yellow solution for intravenous infusion supplied as a carton containing one 40 mg/10 mL (4 mg/mL) single-dose vial.

**Storing and handling DANYELZA:**

Store DANYELZA vial refrigerated at 2 °C to 8 °C (36 °F to 46 °F) in the outer carton to protect from light until time of use.

**Storage recommendation after diluting DANYELZA for infusion:**

If not used immediately, store the diluted DANYELZA infusion solution at room temperature (15 °C to 25 °C [59 °F to 77 °F]) for up to 8 hours or refrigerate (2 °C to 8 °C [36 °F to 46 °F]) for up to 24 hours. Once removed from refrigeration, initiate infusion within 8 hours.

**IMPORTANT SAFETY INFORMATION (continued)**

**CONTRAINDICATION**

DANYELZA is contraindicated in patients with a history of severe hypersensitivity reaction to naxitamab-gqgk. Reactions have included anaphylaxis.

**WARNINGS AND PRECAUTIONS**

**Serious Infusion-Related Reactions**

DANYELZA can cause serious infusion reactions requiring urgent intervention including fluid resuscitation, administration of bronchodilators and corticosteroids, intensive care unit admission, infusion rate reduction or interruption of DANYELZA infusion. Infusion-related reactions included hypotension, bronchospasm, hypoxia, and stridor.

Serious infusion-related reactions occurred in 4% of patients in Study 201 and in 18% of patients in Study 12-230. Infusion-related reactions of any Grade occurred in 100% of patients in Study 201 and 94% of patients in Study 12-230. Hypotension of any grade occurred in 100% of patients in Study 201 and 89% of patients in Study 12-230.

In Study 201, 68% of patients experienced Grade 3 or 4 infusion reactions; and in Study 12-230, 32% of patients experienced Grade 3 or 4 infusion reactions. Anaphylaxis occurred in 12% of patients and two patients (8%) permanently discontinued DANYELZA due to anaphylaxis in Study 201. One patient in Study 12-230 (1.4%) experienced a Grade 4 cardiac arrest 1.5 hours following completion of DANYELZA infusion.

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## **IMPORTANT SAFETY INFORMATION (continued)**

In Study 201, infusion reactions generally occurred within 24 hours of completing a DANYELZA infusion, most often within 30 minutes of initiation. Infusion reactions were most frequent during the first infusion of DANYELZA in each cycle. Eighty percent of patients required reduction in infusion rate and 80% of patients had an infusion interrupted for at least one infusion-related reaction.

Premedicate with an antihistamine, acetaminophen, an H2 antagonist and corticosteroid as recommended. Monitor patients closely for signs and symptoms of infusion reactions during and for at least 2 hours following completion of each DANYELZA infusion in a setting where cardiopulmonary resuscitation medication and equipment are available.

Reduce the rate, interrupt infusion, or permanently discontinue DANYELZA based on severity and institute appropriate medical management as needed.

### **Neurotoxicity**

DANYELZA can cause severe neurotoxicity, including severe neuropathic pain, transverse myelitis, and reversible posterior leukoencephalopathy syndrome.

#### Pain

Pain, including abdominal pain, bone pain, neck pain, and extremity pain, occurred in 100% of patients in Study 201 and 94% of patients in Study 12-230. Grade 3 pain occurred in 72% of patients in Study 201. One patient in Study 201 (4%) required interruption of an infusion due to pain. Pain typically began during the infusion of DANYELZA and lasted a median of less than one day in Study 201 (range less than one day and up to 62 days).

Premedicate with drugs that treat neuropathic pain (e.g., gabapentin) and oral opioids. Administer intravenous opioids as needed for breakthrough pain. Permanently discontinue DANYELZA based on severity.

#### Transverse Myelitis

Transverse myelitis has occurred with DANYELZA. Permanently discontinue DANYELZA in patients who develop transverse myelitis.

#### Reversible Posterior Leukoencephalopathy Syndrome (RPLS)

Reversible posterior leukoencephalopathy syndrome (RPLS) (also known as posterior reversible encephalopathy syndrome or PRES) occurred in 2 (2.8%) patients in Study 12-230. Events occurred 2 and 7 days following completion of the first cycle of DANYELZA. Monitor blood pressure during and following DANYELZA infusion and assess for neurologic symptoms. Permanently discontinue DANYELZA in case of symptomatic RPLS.

#### Peripheral Neuropathy

Peripheral neuropathy, including peripheral sensory neuropathy, peripheral motor neuropathy, paresthesia, and neuralgia, occurred in 32% of patients in Study 201 and in 25% of patients in Study 12-230. Most signs and symptoms of neuropathy began on the day of the infusion and neuropathy lasted a median of 5.5 days (range 0 to 22 days) in Study 201 and 0 days (range 0 to 22 days) in Study 12-230.

Permanently discontinue DANYELZA based on severity.

#### Neurological Disorders of the Eye

Neurological disorders of the eye including unequal pupils, blurred vision, accommodation disorder, mydriasis, visual impairment, and photophobia occurred in 24% of patients in Study 201 and 19% of patients in Study 12-230. Neurological disorders of the eye lasted a median of 17 days (range 0 to 84 days) in Study 201 with two patients (8%) experiencing an event that had not resolved at the time of data cutoff, and a median of 1 day (range less than one day to 21 days) in Study 12-230. Permanently discontinue DANYELZA based on severity.

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## IMPORTANT SAFETY INFORMATION (continued)

### Prolonged Urinary Retention

Urinary retention occurred in 1 (4%) patient in Study 201 and in 3 patients (4%) in Study 12-230. All events in both studies occurred on the day of an infusion of DANYELZA and lasted between 0 and 24 days. Permanently discontinue DANYELZA in patients with urinary retention that does not resolve following discontinuation of opioids.

### **Hypertension**

Hypertension occurred in 44% of patients in Study 201 and 28% of patients in Study 12-230 who received DANYELZA. Grade 3 or 4 hypertension occurred in 4% of patients in Study 201 and 7% of patients in Study 12-230. Four patients (6%) in Study 12-230 permanently discontinued DANYELZA due to hypertension. In both studies, most events occurred on the day of DANYELZA infusion and occurred up to 9 days following an infusion of DANYELZA.

Do not initiate DANYELZA in patients with uncontrolled hypertension. Monitor blood pressure during infusion, and at least daily on Days 1 to 8 of each cycle of DANYELZA and evaluate for complications of hypertension including RPLS. Interrupt DANYELZA infusion and resume at a reduced rate, or permanently discontinue DANYELZA based on the severity.

### **Embryo-Fetal Toxicity**

Based on its mechanism of action, DANYELZA may cause fetal harm when administered to a pregnant woman. Advise females of reproductive potential, including pregnant women, of the potential risk to a fetus. Advise females of reproductive potential to use effective contraceptive during treatment with DANYELZA and for two months after the final dose.

### **ADVERSE REACTIONS**

The most common adverse reactions in Studies 201 and 12-230 ( $\geq 25\%$  in either study) were infusion-related reaction, pain, tachycardia, vomiting, cough, nausea, diarrhea, decreased appetite, hypertension, fatigue, erythema multiforme, peripheral neuropathy, urticaria, pyrexia, headache, injection site reaction, edema, anxiety, localized edema and irritability. The most common Grade 3 or 4 laboratory abnormalities ( $\geq 5\%$  in either study) were decreased lymphocytes, decreased neutrophils, decreased hemoglobin, decreased platelet count, decreased potassium, increased alanine aminotransferase, decreased glucose, decreased calcium, decreased albumin, decreased sodium and decreased phosphate.

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**Reference:** Danyelza. Prescribing information. Y-mAbs Therapeutics Inc; 2020.



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