DANYELZA®
(naxitamab-gqgk)
40mg/10mL Injection

Considerations for Administration and Use

INDICATION

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).

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.**

CONTINUE READING >

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CONTINUE READING >

Information for the administration and use of DANYELZA.

DANYELZA with GM-CSF is the only FDA-approved humanized immunotherapy for patients with high-risk neuroblastoma in the bone and/or bone marrow when response is incomplete to induction or relapse therapy[1]

Frontline Treatment

Induction Therapy | **Consolidation** | **Maintenance**

Incomplete Response
(PR, MR, or SD) with disease in bone and/or bone marrow

↓

DANYELZA®

Relapse

First Relapse Therapy

Incomplete Response
(PR, MR, or SD) with disease in bone and/or bone marrow

↓

DANYELZA®

Incomplete response is defined as partial response (PR), minor response (MR), or stable disease (SD) to prior therapy

IMPORTANT SAFETY INFORMATION

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. CONTINUE READING >

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Information for the administration and use of DANYELZA.

DANYELZA with GM-CSF was granted accelerated approval based on two clinical studies[1]

STUDY 12-230 (single center)[1]

Phase 1/2, open-label, single-arm, single-center trial

- Efficacy analysis included only patients with evaluable disease in bone and/or bone marrow at baseline

N=72; Efficacy analysis (n=38)

STUDY 201 (multicenter)[1,2]

Phase 2, open-label, single-arm, global trial (US, Canada, Denmark, Germany, Italy, Spain, and Hong Kong)

- Efficacy analysis included only patients with evaluable disease in bone and/or bone marrow at baseline

STUDY 201 Initial Analysis[1]*

N=25; Efficacy analysis (n=22)

STUDY 201 Pre-specified Interim Analysis[2]

N=74; Efficacy analysis (n=52)

*Initial analysis included trial sites in the US and Spain only.

INCLUSION CRITERIA (both studies)[1,2]

- High-risk neuroblastoma patients ≥12 months of age with bone and/or bone marrow involvement who had incomplete response to induction or relapse therapy
- Evaluable disease in bone and/or bone marrow
- Patients with prior anti-GD2 therapy permitted
- At least one prior systemic therapy to treat disease outside of the bone and/or bone marrow

EXCLUSION CRITERIA (both studies)[1]

- Actively progressing disease
- Evaluable neuroblastoma outside of the bone/bone marrow

PRIMARY ENDPOINT[1,2]

- Overall response rate

SECONDARY ENDPOINTS

- Duration of response
- Complete response
- Safety

Accelerated approval is based on overall response rate and duration of response.
Continued approval may be contingent upon verification and description of clinical benefit in a confirmatory trial(s).

Treatment with DANYELZA is backed by more than a decade of clinical trial experience and was approved by the FDA in 2020[3]

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS

Serious Infusion-Related Reactions (cont)

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.

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. CONTINUE READING >

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Information for the administration and use of DANYELZA.

DANYELZA overall, complete and partial responses[1,2]

	Study 12-230 (n=38)[1]	Study 201	
		Initial Analysis (n=22)[1]	Pre-specified Interim Analysis*† (n=52)[2]
ORR	34% (13/38) (95% CI: 20, 51)	45% (10/22) (95% CI: 24, 68)	40% (21/52) (95% CI: 27, 55)
CR	26% (10/38)	36% (8/22)	29% (15/52)
PR	8% (3/38)	9% (2/22)	11% (6/52)

Effectiveness of DANYELZA with GM-CSF was evaluated by independent pathology and imaging review. Responses were observed in the bone, bone marrow, or both bone and bone marrow.[1]

*Median follow-up: 5.9 months (range: 0.6–17.8). For the primary endpoint, a sample size of at least 37 patients in the efficacy population is sufficient to ensure at least 90% power to exclude an ORR of 20% or less at the 2-sided 5% level.[2]

†**Limitations: Interim analysis may not be representative of the final analysis.**

CI=confidence interval; CR=complete response; ORR=overall response rate; PR=partial response.

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS

Serious Infusion-Related Reactions (cont)

Caution is advised in patients with pre-existing cardiac disease, as this may exacerbate the risk of severe hypotension.

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. CONTINUE READING >

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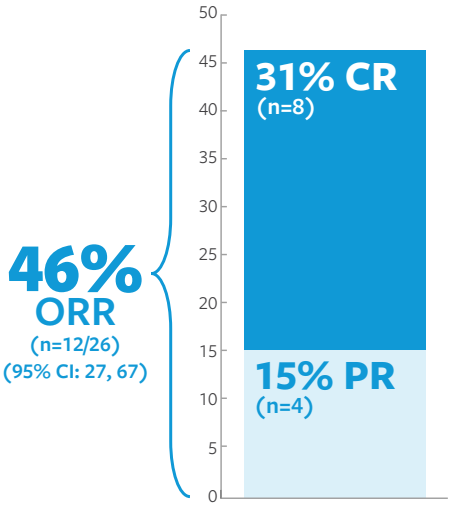
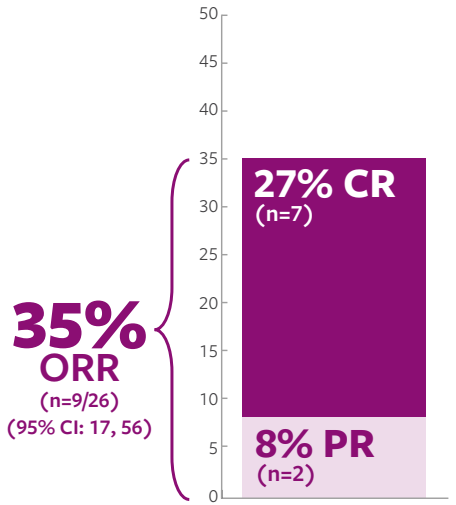
Information for the administration and use of DANYELZA.

DANYELZA Study 201 Pre-specified Interim Analysis: subgroup analyses[2]

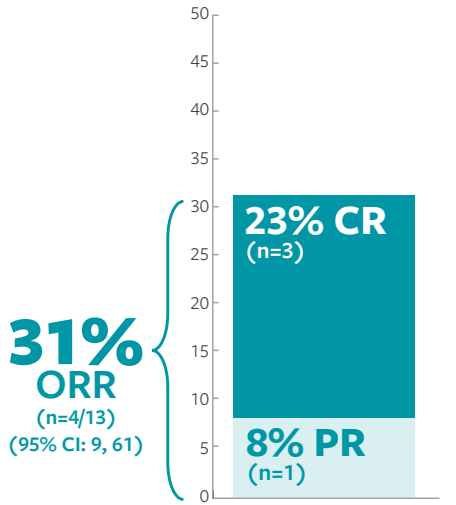
Patients with Incomplete Response to Induction Therapy



Patients with Incomplete Response to Relapse Therapy



Patients with Prior Use of Anti-GD2 Therapy



ORR was defined as a CR or PR according to the revised INRC (2017) *and confirmed by at least 1 subsequent assessment*

Effectiveness of DANYELZA with GM-CSF was evaluated by independent pathology and imaging review. Responses were observed in the bone, bone marrow, or both bone and bone marrow.[2]

Study design: These data underwent pre-specified analyses, including subgroup analyses of the primary endpoint.[2]

Limitations: These subgroup results are based on small sample sizes and could represent chance findings, and they were not adjusted for multiplicity; interpret with caution.[2]

INRC=International Neuroblastoma Response Criteria.

IMPORTANT SAFETY INFORMATION

Neurotoxicity (cont)

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. CONTINUE READING >

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Information for the administration and use of DANYELZA.

Safety analysis of patients who received DANYELZA with GM-CSF[1,2]

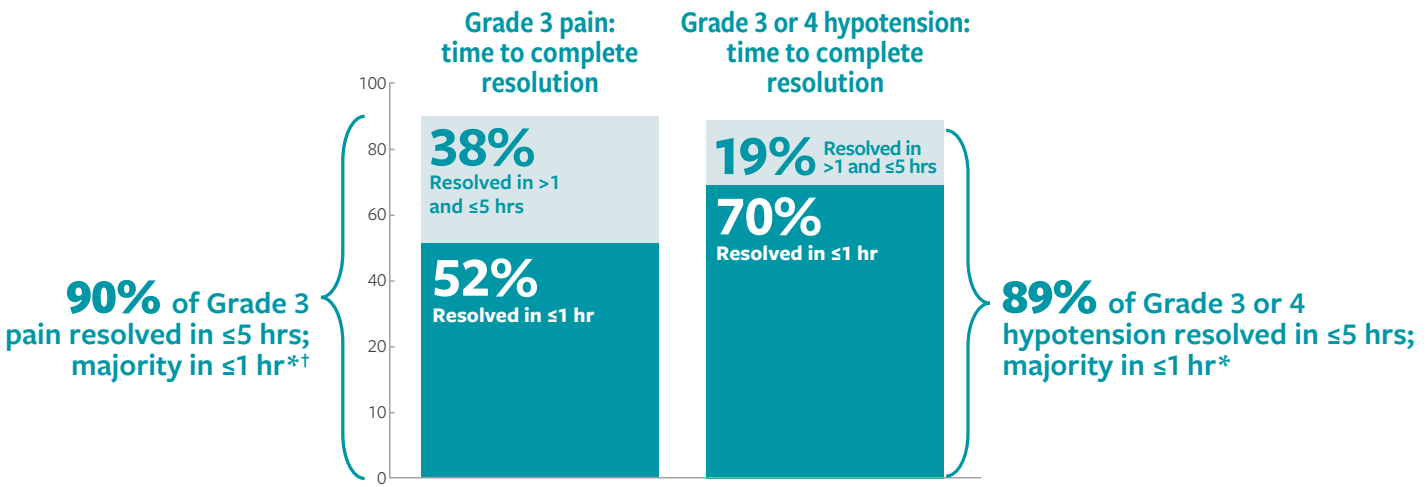
Most common adverse reactions in DANYELZA Study 12-230 and Study 201 Initial and Interim Analyses (≥25% in either study)[1,2]

- Infusion-related reaction
- Pain
- Tachycardia
- Vomiting
- Cough
- Pruritus
- Nausea
- Diarrhea
- Decreased appetite
- Hypertension
- Fatigue
- Erythema multiforme
- Peripheral neuropathy
- Urticaria
- Pyrexia
- Headache
- Injection site reaction
- Edema
- Anxiety
- Localized edema
- Irritability
- Anemia

Total DANYELZA exposure[1,2]

- 12-230: 32% exposed for ≥6 months; 8% for >1 year
- 201 initial analysis: 12% exposed for ≥6 months; 0% for >1 year
- 201 pre-specified interim analysis: 18% exposed for ≥6 months; 3% for ≥1 year

Resolution of select Grade 3 or 4 adverse reactions, Study 201 Pre-specified Interim Analysis[2]



*Incidence of events related to DANYELZA or DANYELZA with GM-CSF occurring on day of infusion, after start of infusion.
†Excludes procedural pain and vessel puncture site pain.

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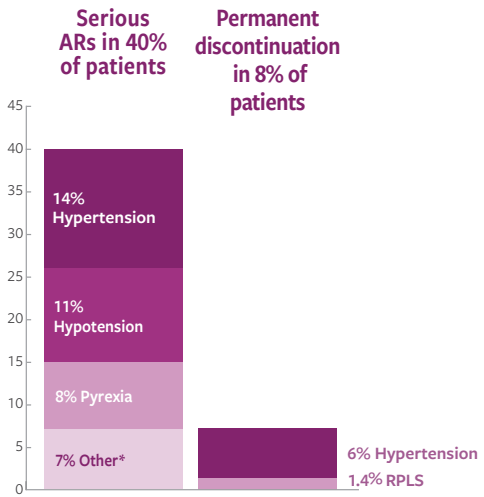
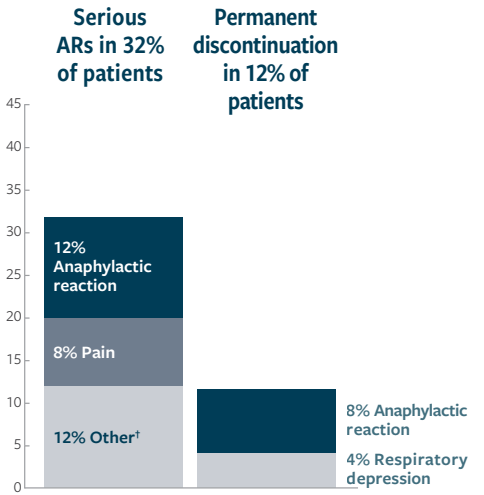
Information for the administration and use of DANYELZA.

Some patients experienced serious adverse reactions that led to permanent discontinuation[1,2]

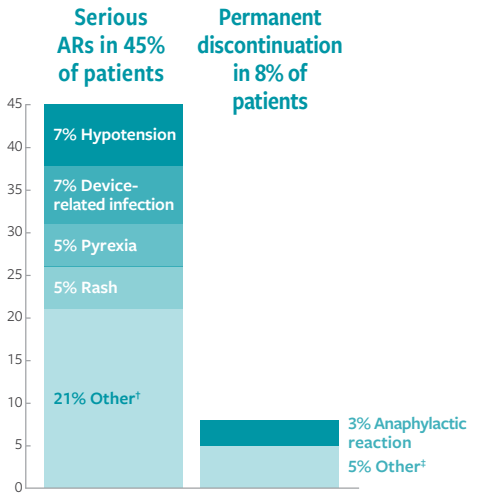
STUDY 12-230 (N=72)[1]



STUDY 201 Initial Analysis (N=25)[1]



STUDY 201 Pre-specified Interim Analysis (N=74)[2]



- In the Study 201 initial analysis, dose interruptions due to an AR occurred in 84% of patients. ARs requiring dosage interruption in >10% of patients included hypotension and bronchospasm[1]
- In the Study 201 pre-specified interim analysis, dose interruptions due to an AR occurred in 69% of patients. ARs requiring dosage interruption in >10% of patients included hypotension, pain, and bronchospasm[2]

*Serious ARs occurring in <5% of patients.
†Serious ARs occurring in only 1 patient.
‡1% each: respiratory depression, myocarditis, hypotension, RPLS, and urticaria.

ARs=adverse reactions; RPLS=reversible posterior leukoencephalopathy syndrome.

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Information for the administration and use of DANYELZA.

When to permanently discontinue DANYELZA[1]

DANYELZA should be discontinued in the case of*:

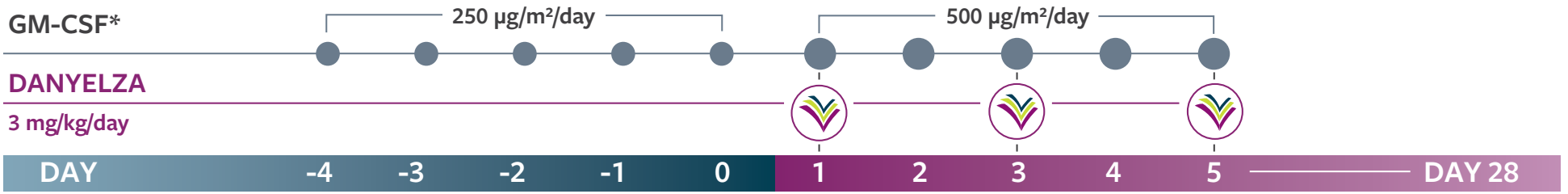
Infusion-related reactions	■ Grade 4, Grade 3 and not responding to medical intervention, or Grade 3-4 anaphylaxis
Pain	■ Grade 3 and unresponsive to maximum supportive measures
Reversible posterior leukoencephalopathy syndrome (RPLS)	■ All grades
Transverse myelitis	■ All grades
Peripheral neuropathy	■ Grade ≥2 motor neuropathy or Grade 3-4 sensory neuropathy
Neurological disorders of the eye	■ Grade 2-4 not resolving within 2 weeks or upon recurrence; any grade with subtotal or total vision loss
Prolonged urinary retention	■ Persisting following discontinuation of opioids
Myocarditis	■ Grade 4, Grade 2 or 3 based on severity and duration
Hypertension	■ Grade 4, or Grade 3 and not responding to medical intervention
Orthostatic hypotension	■ Any grade not resolved within 1 week
Other ARs	■ Grade 4, or Grade 3 not resolving to Grade ≤2 within 2 weeks

*Based on Common Terminology Criteria for Adverse Events (CTCAE) v5.0.

DANYELZA® (naxitamab-gqgk) 40mg/10mL Injection

Information for the administration and use of DANYELZA.

DANYELZA with GM-CSF dosing overview[1]



Pretreatment[1]

GM-CSF

- **Five days before first infusion in each cycle:** initiate GM-CSF by subcutaneous injection for 5 days at 250 µg/m²/day

Day 1 and beyond

GM-CSF

- **Days 1-5 of the DANYELZA infusion, each cycle:** administer GM-CSF at 500 µg/m²/day by subcutaneous injection
- Administer at least 1 hour before DANYELZA on Days 1, 3, and 5

DANYELZA

- Administer on Days 1, 3, 5 of each cycle
- First infusion (Cycle 1, Day 1): administer over 60 minutes
- Subsequent infusions: 30-60 minutes as tolerated

If a DANYELZA dose is missed

Administer the missed dose the following week by Day 10

Administer GM-CSF 500 µg/m²/day on Day 1 of the DANYELZA infusion, and on the day before and the days of the 2nd and 3rd infusions for a total of 5 days with 500 µg/m²/day

*For more details, refer to the GM-CSF Prescribing Information.

IA=interim analysis.

DANYELZA with GM-CSF Treatment Course[1]

Administer until CR or PR +5 more 4-week cycles

May switch to 8-week cycles at the treating physician's discretion

In Study 201 Pre-specified IA
Median # cycles completed 7 cycles
50% of patients studied received 7 or more cycles[2]

Discontinue for disease progression or unacceptable toxicity

IMPORTANT SAFETY INFORMATION

Neurotoxicity (cont)

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. CONTINUE READING >

DANYELZA® (naxitamab-gqgk) 40mg/10mL Injection

Information for the administration and use of DANYELZA.

Administering premedications and supportive medications

Premedications and supportive medications for pain[1]

Five days prior to the first infusion of DANYELZA in each cycle:

- Initiate a 12-day course (Day -4 through Day 7) of prophylactic medication for neuropathic pain, such as gabapentin

On the day of each DANYELZA infusion:

		~5h 2 HRS PRIOR	60-45 MIN PRIOR	30 MIN PRIOR	~60 MIN INFUSION*	2 HRS POST
PAIN	Gabapentin†	Ongoing, started at Day -4				2-hour postinfusion observation required
PAIN	Opioids‡		Oral		IV as needed‡	
PAIN	Ketamine§				Consider as needed§	

*60-minute first infusion of DANYELZA (Cycle 1, Day 1), and subsequently 30-60 minutes as tolerated.
†Or other prophylactic medication for neuropathic pain.
‡Administer IV opioids as needed for breakthrough pain.
§Consider for pain not adequately controlled by opioids.

IV=intravenous.

IMPORTANT SAFETY INFORMATION

Neurotoxicity (cont)

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. CONTINUE READING >

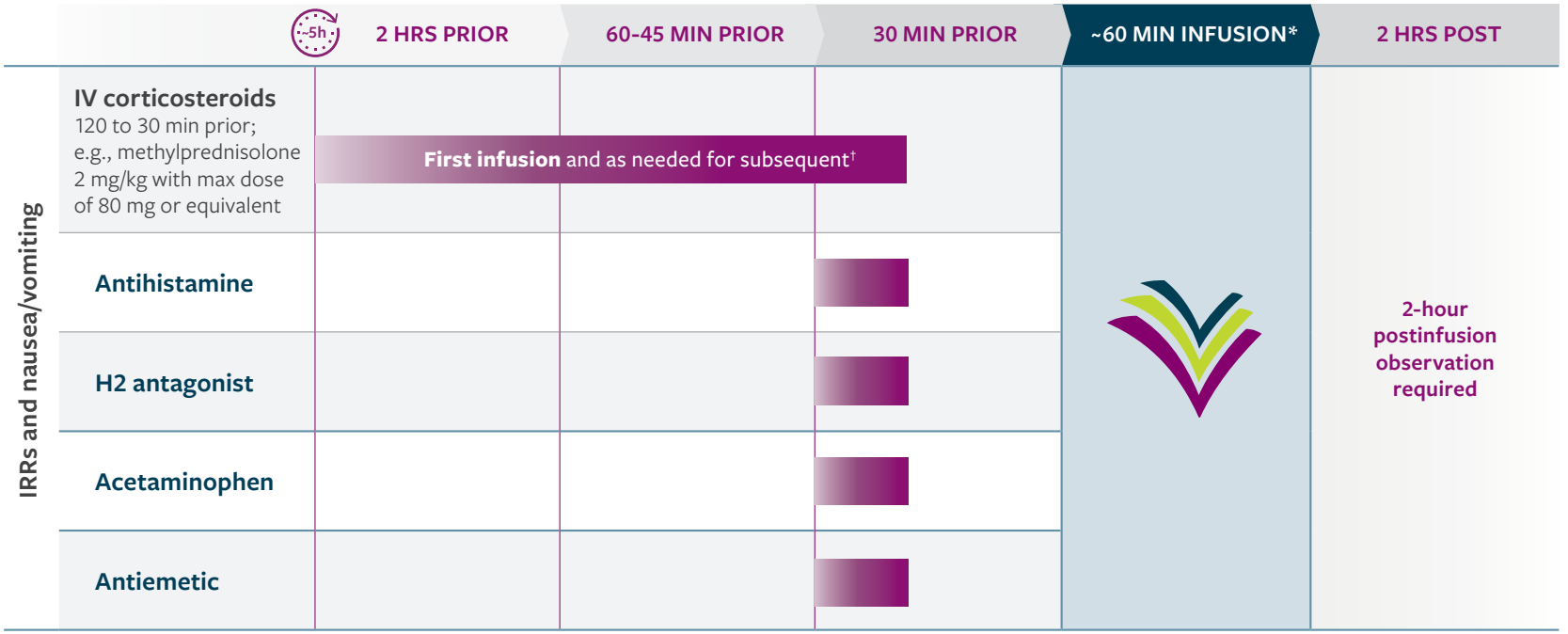
DANYELZA® (naxitamab-gqgk) 40mg/10mL Injection

Information for the administration and use of DANYELZA.

Administering premedications and supportive medications

Premedications for infusion-related reactions, nausea/vomiting[1]

On the day of each DANYELZA infusion:



*60-minute first infusion of DANYELZA (Cycle 1, Day 1), and subsequently 30-60 minutes as tolerated.
†Or other prophylactic medication for neuropathic pain.

IRRs=infusion-related reactions.

IMPORTANT SAFETY INFORMATION

Neurotoxicity (cont)

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. CONTINUE READING >

DANYELZA® (naxitamab-gqgk) 40mg/10mL Injection

Information for the administration and use of DANYELZA.

Key considerations for DANYELZA with GM-CSF administration

DANYELZA treatment course[1]	DANYELZA infusion setting[2]	Premedications and supportive medications[1]
4-week cycles until CR or PR[1] Then administered for **+ 5 more cycles** Subsequently, may switch to 8-week cycles*	**Outpatient or inpatient** at the treating physician's discretion	**Required** for infusion-related reactions, nausea and vomiting, pain
	DANYELZA infusion duration[1]	**Post-infusion observation[1]**
	60-minute first infusion Subsequently, 30-60 minutes as tolerated	**Required for ≥2 hours** after each DANYELZA infusion in a setting where cardio-pulmonary resuscitation medication and equipment are available

*At the discretion of the treating physician.

IMPORTANT SAFETY INFORMATION

Neurotoxicity (cont)

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.

Myocarditis

Myocarditis has occurred in adolescent patients receiving DANYELZA in clinical trials and expanded access programs. Myocarditis occurred within days of receiving DANYELZA requiring drug interruption. Monitor for signs and symptoms of myocarditis during treatment with DANYELZA. Withhold, reduce the dose, or permanently discontinue DANYELZA based on severity. CONTINUE READING >

DANYELZA® (naxitamab-gqgk) 40mg/10mL Injection

Information for the administration and use of DANYELZA.

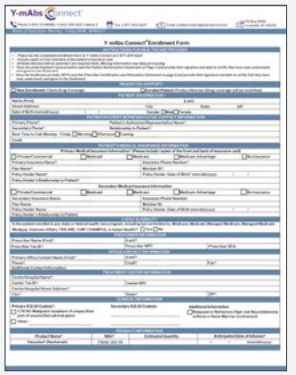
Getting your patients started on DANYELZA*

Y-mAbs Connect®

Your link to patient support

1 Enroll patient in Y-mAbs Connect®	■ **Visit** 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	■ **Place an order** for DANYELZA through a participating specialty distributor using the patient-unique ID from Y-mAbs Connect
3 Receive the DANYELZA shipment	■ **Receive** the DANYELZA shipment at the infusion site

Enrollment form available for download



*While patients need to be enrolled in Y-mAbs Connect prior to ordering DANYELZA, completing and returning the enrollment form does not require a commitment to order DANYELZA. The Y-mAbs Connect Enrollment Form is not a prescription for DANYELZA.

†Y-mAbs Connect case managers could provide insurance verification.

DANYELZA® (naxitamab-gqgk) 40mg/10mL Injection

DANYELZA is the only FDA-approved therapy indicated to treat high-risk neuroblastoma in the bone and/or bone marrow for patients who have[1]:

- Incomplete response* to **induction** therapy

or

- Incomplete response* to **relapse** therapy

Flexible administration[1,2]

- May be administered in the outpatient or inpatient setting, at the discretion of the treating physician[2]
- First infusion 60 minutes (30-60 minutes thereafter)[1]

Backed by >10 years of clinical trial experience and approved by the FDA in 2020[1,3†]

Administered at an expanding nationwide network[2]

65+ US Healthcare Institutions[2] AND GROWING

Access valuable clinical resources, from expert videos to a variety of downloadable materials.

*Incomplete response is defined as partial response, minor response, or stable disease to prior therapy.
†Accelerated approval.

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.**

CONTINUE READING >

References: 1. DANYELZA® [package insert]. New York, NY: Y-mAbs Therapeutics, Inc.; 2024. Available online at https://labeling.ymabs.com/danyelza. **2.** Data on file. Y-mAbs Therapeutics, Inc. **3.** NIH US National Library of Medicine. https://clinicaltrials.gov/ct2/show/NCT01419834?term=NCT01419834&draw=2&rank=1. Accessed April 22, 2024.

DANYELZA® (naxitamab-gqgk) 40mg/10mL Injection

DANYELZA®
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Infusion Checklist

Important information to facilitate DANYELZA administration

INDICATION

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.

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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.**

CONTINUE READING >

The purpose of this checklist is to help prepare for a DANYELZA infusion, including: premedications and supportive medications and their sequence; supplies to have available; and post-infusion measures and monitoring. Please see the full Prescribing Information for further dosing and administration information.

DANYELZA can cause serious infusion-related reactions and severe neuropathic pain. Administer premedication and supportive medication, as appropriate, before and during infusion.[1]

Prior to infusion day[1]

- ☐ Review notes from previous infusion, if applicable
- ☐ **Prophylactic medication for neuropathic pain (e.g., gabapentin):** Beginning 5 days prior to the first infusion of DANYELZA in each cycle, initiate a 12-day course (Day -4 through Day 7)
- ☐ **Granulocyte-macrophage colony-stimulating factor (GM-CSF):** Beginning 5 days prior to the first infusion of DANYELZA in each cycle, administer GM-CSF 250 µg/m^2/day by subcutaneous injection (Day -4 through Day 0)

Day of infusion[1]

GM-CSF

- ☐ Beginning Day 1 of the first infusion of DANYELZA in each cycle, administer GM-CSF at 500 µg/m^2/day by subcutaneous injection (Day 1 through Day 5)
- ☐ Ensure that GM-CSF is administered **≥1 hour prior to infusion** on days of DANYELZA infusion (Days 1, 3, and 5)

Preparing for infusion: Premedication and supportive medication

Infusion-Related Reactions and Nausea/Vomiting

- ☐ 1. Corticosteroids
  30 minutes to 2 hours prior to the first infusion of DANYELZA:
  - First infusion: Administer intravenous (IV) corticosteroids (e.g., methylprednisolone 2 mg/kg with a maximum dose of 80 mg or equivalent corticosteroid dose)
  - Subsequent infusions: Administer corticosteroid premedication if a severe infusion reaction occurred with the previous infusion or during the previous cycle
- ☐ 2. Antihistamine
  30 minutes prior to each infusion
- ☐ 3. H2 antagonist
  30 minutes prior to each infusion
- ☐ 4. Acetaminophen
  30 minutes prior to each infusion
- ☐ 5. Antiemetic
  30 minutes prior to each infusion

IMPORTANT SAFETY INFORMATION

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. CONTINUE READING >

DANYELZA® (naxitamab-gqgk) 40mg/10mL Injection

DANYELZA can cause serious infusion-related reactions and severe neuropathic pain. Administer premedication and supportive medication, as appropriate, before and during infusion.[1]

Day of infusion[1] (cont)

Preparing for infusion: Premedication and supportive medication (cont)

Pain Management

☐ Oral opioids
45-60 minutes prior to initiation of each DANYELZA infusion

Supplies to have available during infusion*

- Oxygen mask
- Continuous pulse oximeter machine and probe
- Nebulizer kits
- Blood pressure machine/monitor
- Emergency equipment
- Cardiopulmonary resuscitation medication and equipment

*Other supplies may be required. Follow your institution's guidelines.

During infusion†

☐ Days 1, 3, and 5: Administer DANYELZA 3 mg/kg/day (up to 150 mg/day) by IV infusion after dilution
- 60-minute first infusion (Cycle 1, Day 1) and subsequently 30-60 minutes as tolerated

Infusion-Related Reactions

☐ **Monitor closely for adverse reactions (see list of adverse reactions on page 19)**

☐ **Urgent intervention may include:**
- Fluid resuscitation
- Symptomatic treatment (e.g., antihistamines, NSAIDs, narcotics)
- Administration of bronchodilators and corticosteroids
- Intensive care unit admission
- Infusion rate reduction
- Interruption of DANYELZA infusion

Pain Management

☐ Opioids
- Administer additional IV opioids as needed for breakthrough pain during infusion

☐ Ketamine
- Consider use of ketamine for pain not adequately controlled by opioids

☐ Pain scales for children
- To help gauge pain effectively during infusion, consider using the **Wong-Baker FACES® Pain Rating Scale** or the **FLACC Behavioral Pain Scale.** Please follow your institution's guidelines

†For recommended dose modifications, please refer to the accompanying full Prescribing Information.

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS

Serious Infusion-Related Reactions (cont)

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.

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. CONTINUE READING >

DANYELZA® (naxitamab-gqgk) 40mg/10mL Injection

DANYELZA can cause serious infusion-related reactions and severe neuropathic pain. Administer premedication and supportive medication, as appropriate, before and during infusion.[1]

After infusion[1]

Post-infusion measures and patient monitoring

- ☐ Continue to monitor patients for adverse reactions for a minimum of 2 hours following each DANYELZA infusion in a setting where cardiopulmonary resuscitation medication and equipment are available **(see list of adverse reactions below line)**
- ☐ Document any pertinent information in the patient's chart (e.g., infusion rate changes, supportive measures)
- ☐ Provide home instructions to the patient and caregiver, including when to call the physician
- ☐ Set expectations for the next DANYELZA infusion and what follow-up will be necessary
- ☐ Advise the patient and caregiver to read the FDA-approved patient labeling (Patient Information)

Monitor for adverse reactions, including:

- **Serious infusion-related reactions (IRRs):** Symptoms of serious IRRs include hypotension, bronchospasm, hypoxia, and stridor. In clinical trials, onset was generally within 24 hours of infusion, most often within 30 minutes of initiating infusion, and most frequent during the first infusion of DANYELZA in each cycle. Serious IRRs may require urgent intervention, including fluid resuscitation, administration of bronchodilators and corticosteroids, intensive care unit admission, infusion rate reduction, or interruption of DANYELZA infusion
- **Hypertension and neurologic symptoms:** Monitor blood pressure during the infusion, and at least daily on Days 1 through 8 of each cycle to assess for complications of hypertension, including neurologic reversible posterior leukoencephalopathy syndrome (RPLS)
- **Myocarditis:** Monitor for symptoms such as chest pain, shortness of breath, or abnormal heart rhythms
- **Orthostatic hypotension:** Monitor blood pressure and assess for signs and symptoms, including dizziness, lightheadedness, or fainting
- **Lab abnormalities:** Monitor for lab abnormalities, including cytopenia, changes in glucose, liver, and cardiac abnormalities

Please see the full Prescribing Information for the full list of clinically significant adverse reactions and dosage modifications for adverse reactions.

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS

Serious Infusion-Related Reactions (cont)

Caution is advised in patients with pre-existing cardiac disease, as this may exacerbate the risk of severe hypotension.

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.

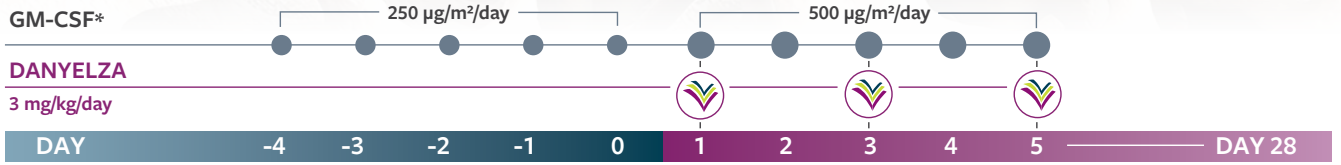
Reduce the rate, interrupt infusion, or permanently discontinue DANYELZA based on severity and institute appropriate medical management as needed.

Neurotoxicity

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

DANYELZA® (naxitamab-gqgk) 40mg/10mL Injection

DANYELZA with GM-CSF overview[1]



*For more details, refer to the GM-CSF Prescribing Information.

DANYELZA with GM-CSF Treatment Course[1]

Administer until ***CR or PR*** **+5 more 4-week cycles**

May switch to 8-week cycles at the treating physician's discretion

Discontinue for disease progression or unacceptable toxicity

Access valuable clinical resources, from expert videos to a variety of downloadable materials, on managing DANYELZA infusion-related reactions.

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.**

CONTINUE READING >

Reference: 1. DANYELZA® [package insert]. New York, NY: Y-mAbs Therapeutics, Inc.; 2024. Available online at https://labeling.ymabs.com/danyelza.

DANYELZA® (naxitamab-gqgk) 40mg/10mL Injection

DANYELZA®
(naxitamab-gqgk)
40mg/10mL Injection

Dosage Modifications and Adverse Event Management Guide

INDICATION

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).

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.**

CONTINUE READING >

Monitor patients during and after the DANYELZA infusion.

See back page for definitions/descriptions of Common Terminology Criteria for Adverse Events (CTCAE) severity scale.

Dose modifications for managing adverse reactions[1]

Adverse Reaction	Severity	Action
Infusion-related reactions	**Grade 2** ■ Responds promptly to symptomatic treatment	🟡 Reduce infusion rate to 50%, monitor until Grade ≤1 🟢 Gradually increase infusion rate
	Grade 3 ■ Prolonged, recurrent, or hospitalization indicated	🟡 Interrupt and monitor until Grade ≤2 🟢 Resume at 50% rate, increase gradually
	Grade 3 ■ Not responding to medical intervention	🔴 Permanently discontinue
	Grade 4 ■ Life-threatening	🔴 Permanently discontinue
Anaphylaxis	**Grade 3 or 4**	🔴 Permanently discontinue
Pain	**Grade 3** unresponsive to maximum supportive measures	🔴 Permanently discontinue
RPLS	**All grades**	🔴 Permanently discontinue
Transverse myelitis	**All grades**	🔴 Permanently discontinue

Adverse reactions were graded and defined using Common Terminology Criteria for Adverse Events version 5.0.[2]
RPLS=reversible posterior leukoencephalopathy syndrome.

DANYELZA® (naxitamab-gqgk) 40mg/10mL Injection

Monitor patients during and after the DANYELZA infusion.

See back page for definitions/descriptions of Common Terminology Criteria for Adverse Events (CTCAE) severity scale.

Dose modifications for managing adverse reactions[1]

Adverse Reaction	Severity	Action
Peripheral neuropathy	**Grade ≥2** motor neuropathy or **Grade 3-4** sensory neuropathy	Permanently discontinue
Neurological disorders of the eye	**Grade 2-4** resulting in decreased visual acuity or limiting ADL	Withhold until resolved Resume at 50% dose; gradually increase to prior dose
	Grade 2-4 not resolved in ≤2 weeks	Permanently discontinue
	Subtotal or total vision loss	Permanently discontinue
Prolonged urinary retention	**Persisting** after opioid discontinuation	Permanently discontinue
Myocarditis	**Grade 2 or 3**	Withhold, reduce dose, or permanently discontinue based on severity and duration
	Grade 4	Permanently discontinue

Adverse reactions were graded and defined using Common Terminology Criteria for Adverse Events version 5.0.[2]
ADL=activities of daily life.

DANYELZA® (naxitamab-gqgk) 40mg/10mL Injection

Monitor patients during and after the DANYELZA infusion.

See back page for definitions/descriptions of Common Terminology Criteria for Adverse Events (CTCAE) severity scale.

Dose modifications for managing adverse reactions[1]

Adverse Reaction	Severity	Action
Hypertension Do not initiate DANYELZA in patients with uncontrolled hypertension	**Grade 3** ■ Pediatric and adolescent: systolic and/or diastolic BP >5 mmHg above the 99th percentile[2] ■ Adult: medical intervention indicated (systolic BP ≥160 mmHg or diastolic ≥100 mmHg)[2]	● Withhold until recovery to Grade ≤2 ● Resume infusion at 50% prior rate; gradually increase rate
	Grade 3 ■ Not responding to medical intervention	● Permanently discontinue
	Grade 4 ■ Life-threatening	● Permanently discontinue
Orthostatic hypotension	**All grades**	● Withhold DANYELZA until recovery to Grade ≤1 ● If resolved in ≤1 week, restart at 50% prior dose Subsequent cycles: resume at recommended dose
	Any grade not resolved in ≤1 week	● Permanently discontinue
Other adverse reactions	**Grade 3** ■ Severe or medically significant but not immediately life-threatening ■ Hospitalization or prolongation of hospitalization indicated; disabling; limiting self-care ADL	● Withhold DANYELZA until recovery to Grade ≤2 ● If resolved to Grade ≤2, resume DANYELZA at same rate ● Permanently discontinue if not resolved to Grade ≤2 within 2 weeks
	Grade 4 ■ Life-threatening	● Permanently discontinue

Adverse reactions were graded and defined using Common Terminology Criteria for Adverse Events version 5.0.[2]
ADL=activities of daily life; BP=blood pressure.

DANYELZA® (naxitamab-gqgk) 40mg/10mL Injection

Because DANYELZA can cause serious drug- and infusion-related reactions that require immediate medical attention, it is important that you and your patients' caregivers remain vigilant and observant.

Post-infusion monitoring[1]

Observation is required for at least 2 hours after the DANYELZA infusion in a setting where cardiopulmonary resuscitation medication and equipment are available

Serious infusion-related reactions (IRRs)

- Symptoms of serious IRRs include hypotension, bronchospasm, hypoxia, and stridor
- In clinical trials, onset was generally within 24 hours of infusion, most often within 30 minutes of initiating infusion, and most frequent during the first infusion of DANYELZA in each cycle
- Serious IRRs may require urgent intervention, including fluid resuscitation, administration of bronchodilators and corticosteroids, intensive care unit admission, infusion rate reduction, or interruption of DANYELZA infusion

Actor portrayals

Hypertension and neurologic symptoms: Monitor blood pressure during the infusion, and at least daily on Days 1 through 8 of each cycle to assess for complications of hypertension, including neurologic RPLS

Myocarditis: Monitor for symptoms such as chest pain, shortness of breath, or abnormal heart rhythms

Myocarditis has occurred in adolescent patients within days of receiving DANYELZA

Orthostatic hypotension: Monitor blood pressure and assess for signs and symptoms, including dizziness, lightheadedness, or fainting

Lab abnormalities: Monitor for lab abnormalities, including cytopenia, changes in glucose, liver, and cardiac abnormalities

RPLS=reversible posterior leukoencephalopathy syndrome.

DANYELZA® (naxitamab-gqgk) 40mg/10mL Injection

Because DANYELZA can cause serious drug- and infusion-related reactions that require immediate medical attention, it is important that you and your patients' caregivers remain vigilant and observant.

Patient counseling[1]

Advise patients and caregivers to immediately contact their HCP for any new or worsening adverse reactions that occur during or after the DANYELZA infusions, including the following:

- **IRRs:** Facial or lip swelling, itching, rash, trouble breathing, cough/wheezing, dizziness
- **Severe pain:** Including pain in the belly, bone, neck, legs, or arms, weakness in arms or legs
- **Inflammation of the spinal cord:** Including weakness in arms or legs, bladder and bowel problems, pain in back, legs, or stomach, numbness, tingling, burning sensation
- **RPLS:** Severe headache, vision changes, confusion or disorientation, decreased alertness, difficulty speaking, weakness in arms or legs, seizures

Actor portrayals

- **Neurological eye disorders:** Unequal pupil size, blurred vision, mydriasis, visual impairment, photophobia
- **Prolonged urinary retention:** Problems urinating or emptying the bladder
- **Myocarditis:** Chest pain, shortness of breath, or abnormal heart rhythms
- **Orthostatic hypotension:** Dizziness, lightheadedness or fainting, especially when standing after sitting or lying down

IRRs=infusion-related reactions; RPLS=reversible posterior leukoencephalopathy syndrome.

DANYELZA® (naxitamab-gqgk) 40mg/10mL Injection

Common terminology criteria for adverse events (CTCAE)[2]

The CTCAE system, a product of the US National Cancer Institute (NCI), allows standardized classification of severity of adverse events associated with drugs and treatment used in cancer therapy. Use this grade scale to determine appropriate dose modifications as prescribed on pages 22-24 of this booklet.

Grade	Severity	Description
Grade 1	Mild	■ Asymptomatic or mild symptoms; clinical or diagnostic observations only; intervention not indicated
Grade 2	Moderate	■ Minimal, local, or noninvasive intervention indicated
Grade 3	Severe	■ Severe or medically significant but not immediately life-threatening ■ Hospitalization or prolongation of hospitalization indicated
Grade 4	Life-threatening	■ Life-threatening consequences ■ Urgent intervention indicated
Grade 5	Death related to adverse events	■ Grade 5 is not appropriate for some adverse events and is therefore not an option

Access valuable clinical resources, from expert videos to a variety of downloadable materials, on managing DANYELZA infusion-related reactions.

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.**

CONTINUE READING >

References: 1. DANYELZA® [package insert]. New York, NY: Y-mAbs Therapeutics, Inc.; 2024. Available online at https://labeling.ymabs.com/danyelza.
2. Common terminology criteria for adverse events (CTCAE). Version 5.0. Published 11/27/2017.

DANYELZA® (naxitamab-gqgk) 40mg/10mL Injection

Indication and Important Safety Information

INDICATION

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).

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.**

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.

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.

Caution is advised in patients with pre-existing cardiac disease, as this may exacerbate the risk of severe hypotension. CONTINUE READING >

DANYELZA® (naxitamab-gqgk) 40mg/10mL Injection

Important Safety Information (cont)

WARNINGS AND PRECAUTIONS

Serious Infusion-Related Reactions (cont)

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.

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. CONTINUE READING >

DANYELZA® (naxitamab-gqgk) 40mg/10mL Injection

Important Safety Information (cont)

WARNINGS AND PRECAUTIONS

Myocarditis

Myocarditis has occurred in adolescent patients receiving DANYELZA in clinical trials and expanded access programs. Myocarditis occurred within days of receiving DANYELZA requiring drug interruption. Monitor for signs and symptoms of myocarditis during treatment with DANYELZA. Withhold, reduce the dose, or permanently discontinue DANYELZA based on severity.

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.

Orthostatic Hypotension

Orthostatic hypotension has occurred in patients receiving DANYELZA in clinical trials and expanded access programs. Severe orthostatic hypotension, including cases requiring hospitalization, have occurred. Cases occurred within hours to 6 days of DANYELZA infusions in any cycle.

In patients with symptoms of orthostatic hypotension, monitor postural blood pressure prior to initiating treatment with DANYELZA and as clinically indicated with subsequent dosing. Withhold, reduce dose, or permanently discontinue DANYELZA based on 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 last dose.

ADVERSE REACTIONS

The most common adverse reactions in Studies 201 and 12-230 (≥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 (≥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.

Please click for full Prescribing Information and Patient Information for DANYELZA including Boxed Warning on serious infusion-related reactions and neurotoxicity.

To review important state-specific disclosure information for licensed healthcare practitioners, please visit https://www.ymabs.com/information-for-prescribers

DANYELZA® (naxitamab-gqgk) 40mg/10mL Injection

Prescribing Information

https://labeling.ymabs.com/danyelza