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

NURSE POCKET GUIDE FOR DANYELZA®

Infusion and potential adverse reactions

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.**

Please see additional Important Safety Information inside. Please see accompanying full Prescribing Information and Patient Information for DANYELZA including Boxed Warning on serious infusion-related reactions and neurotoxicity.

-mAbs Therapeutics, Inc.™

DANYELZA® is the first and only humanized GD2-binding immunotherapy approved by the FDA[1]

Mechanism of Action

DANYELZA is a humanized monoclonal antibody that targets GD2 and was shown to induce complement-dependent cytotoxicity (CDC) and antibody-dependent cell-mediated cytotoxicity (ADCC) in vitro. GD2 is a disialoganglioside that is overexpressed on neuroblastoma cells and other cells of neuroectodermal origin, including the central nervous system and peripheral nerves.

Immunogenicity

Humanization may help make DANYELZA less likely to be identified as foreign by the immune system.[2,3] However, as with all therapeutic proteins, there is the potential for immunogenicity.

- In Study 201, 2 of 24 (8%) patients tested positive for ADA after treatment with DANYELZA
- In Study 12-230, 27 of 117 (23%) tested positive for ADA after treatment with DANYELZA by an assay that was not fully validated; therefore the incidence of ADA may not be reliable

DANYELZA was studied in an outpatient setting[4]

ADA=anti-drug antibodies.

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

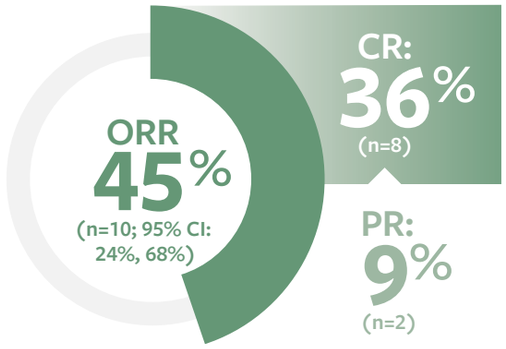
Serious Infusion-Related Reactions

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.

Please see additional Important Safety Information throughout. Please see accompanying full Prescribing Information and Patient Information for DANYELZA including Boxed Warning on serious infusion-related reactions and neurotoxicity.

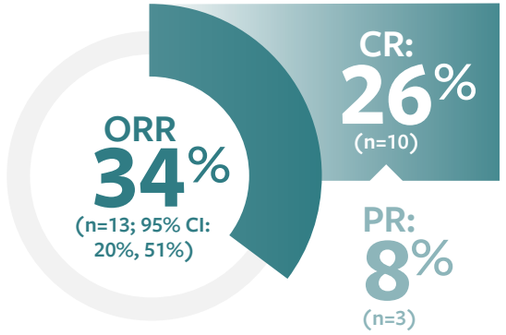
In some patients, DANYELZA® can provide a road to remission with OR and CR rates shown in clinical trials[1,5]

Study 201 EFFICACY RESULTS (n=22)



Study 201 design: The efficacy of DANYELZA in combination with GM-CSF was evaluated in Study 201, a multicenter, open-label, single-arm trial, in a subpopulation of patients who had refractory or relapsed high-risk neuroblastoma in the bone or bone marrow and demonstrated a PR, MR, or SD to prior therapy. Patients with progressive disease were excluded.

Study 12-230 EFFICACY RESULTS (n=38)



Study 12-230 design: The efficacy of DANYELZA in combination with GM-CSF was evaluated in Study 12-230, a single-center, open-label, single-arm trial, in a subpopulation of patients who had relapsed or refractory high-risk neuroblastoma in the bone or bone marrow and demonstrated a PR, MR, or SD to prior therapy. Patients with progressive disease were excluded.

CR=complete response; MR=minor response; OR=overall response; ORR=overall response rate; PR=partial response; SD=stable disease.

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Safety considerations for DANYELZA®[1]

Contraindication

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

Use in specific populations

Pregnancy: DANYELZA may cause fetal harm when administered to pregnant women. There are no available data on the use of DANYELZA in pregnant women and no animal reproduction studies have been conducted with DANYELZA.

Lactation: There are no data on the presence of naxitamab-gqgk in human milk or its effects on the breastfed child, or on milk production; however, human IgG is present in human milk. Because of the potential for serious ARs in a breastfed child from DANYELZA, advise women not to breastfeed during treatment and for 2 months after the final dose of DANYELZA

Females and Males of Reproductive Potential: DANYELZA may cause fetal harm when administered to a pregnant woman. Verify pregnancy status in females of reproductive potential prior to initiating DANYELZA and advise to use effective contraception during treatment and for 2 months after the final dose.

Pediatric and Geriatric Use: The safety and effectiveness of DANYELZA in combination with GM-CSF have been established in pediatric patients 1 year of age or older. Clinical studies of DANYELZA in combination with GM-CSF did not include patients 65 years of age and older.

IMPORTANT SAFETY INFORMATION

Serious Infusion-Related Reactions (cont'd)

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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DANYELZA® in combination with GM-CSF safety profile[1]

Study 201 (N=25)

- Serious adverse reactions (ARs) were reported in 32% of patients; serious ARs in more than 1 patient included anaphylactic reaction (12%) and pain (8%)
- Permanent discontinuation of DANYELZA due to an AR was reported in 12% of patients; ARs resulting in permanent discontinuation of DANYELZA in 1 or more patients included anaphylactic reaction (8%) and respiratory depression (4%)
  - —Dose interruptions due to an AR occurred in 84% of patients; ARs requiring dosage interruption in >10% of patients included hypotension and bronchospasm
- Infusion-related reactions and pain were reported in 100% of patients
- Clinically relevant ARs occurring in ≤10% of patients who received DANYELZA with GM-CSF included peripheral edema (8%)

Study 12-230 (N=72)

- Serious ARs were reported in 40% of patients; serious ARs in >5% of patients included hypertension (14%), hypotension (11%), and pyrexia (8%)
- Permanent discontinuation of DANYELZA due to an AR occurred in 8% of patients; 4 (6%) patients permanently discontinued DANYELZA due to hypertension and 1 (1.4%) patient discontinued due to reversible posterior leukoencephalopathy syndrome
- Infusion-related reactions and pain were reported in 94% of patients
- Clinically relevant ARs in ≤10% of patients who received DANYELZA with GM-CSF included apnea (4.2%), hypopnea (2.8%), generalized edema (2.8%), peripheral edema (8.3%), and device-related infection (4.2%)

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DANYELZA® with GM-CSF: adverse reactions observed (>10%)[1]

Adverse Reaction System organ class/preferred term	STUDY 201 N=25		STUDY 12-230[a] N=72	
	All Grades %	Grade 3 or 4 %	All Grades %	Grade 3 or 4 %
General disorders and administration site conditions				
Pain[b]	100%	72%	94%	2.8%
Infusion-related reaction[c]	100%	68%	94%	32%
Edema	28%	0%	N/A	N/A
Fatigue[d]	28%	0%	44%	0%
Pyrexia[e]	28%	0%	11%	0%
Injection site reaction	N/A	N/A	28%	0%
Localized edema	N/A	N/A	25%	0%
Respiratory, thoracic, and mediastinal disorders				
Cough	60%	0%	57%	0%
Rhinorrhea	24%	0%	15%	0%
Oropharyngeal pain	N/A	N/A	15%	0%
Vascular disorders				
Hypertension	44%	4%	28%	7%
Gastrointestinal disorders				
Vomiting	60%	4%	63%	2.8%
Diarrhea	56%	8%	50%	4.2%
Nausea	56%	0%	57%	1.4%
Constipation	N/A	N/A	15%	0%
Skin and subcutaneous tissue disorders				
Urticaria[f]	32%	4%	N/A	N/A
Erythema multiforme	N/A	N/A	33%	0%
Hyperhidrosis	N/A	N/A	17%	0%
Erythema	N/A	N/A	11%	0%
Cardiac disorders				
Tachycardia[g]	84%	4%	N/A	N/A
Sinus tachycardia	N/A	N/A	44%	1.4%
Nervous system disorders				
Peripheral neuropathy[h]	32%	0%	25%	0%
Headache	28%	8%	18%	0%
Depressed level of consciousness	24%	16%	N/A	N/A
Lethargy	N/A	N/A	14%	0%
Eye disorders				
Neurological disorders of the eye[i]	24%	0%	19%	0%
Immune system disorders				
Anaphylactic reaction	12%	12%	N/A	N/A
Metabolism and nutrition disorders				
Decreased appetite	16%	0%	53%	4.2%
Infections and infestations				
Influenza	12%	0%	N/A	N/A
Rhinovirus infection	12%	0%	14%	0%
Upper respiratory tract infection	12%	0%	N/A	N/A
Enterovirus infection	N/A	N/A	13%	0%
Investigations				
Weight decreased	12%	0%	N/A	N/A
Breath sounds abnormal	N/A	N/A	15%	0%
Psychiatric disorders				
Anxiety	12%	0%	26%	0%
Irritability	N/A	N/A	25%	0%
Injury and procedural complications				
Contusion	N/A	N/A	15%	0%

Adverse reactions were graded using CTCAE version 4.0.

CTCAE=Common Terminology Criteria for Adverse Events; N/A=not applicable.

[a]All adverse reactions occurring in Cycles 1 and 2, and adverse reactions of Grade ≥3 severity occurring in subsequent cycles were reported. In the dose-finding phase, Grade 2 unexpected adverse reactions were also reported for Cycles 3 and later.

[b]Pain includes pain, abdominal pain, pain in extremity, bone pain, neck pain, back pain, non-cardiac chest pain, flank pain, and musculoskeletal pain.

[c]Infusion-related reaction includes hypotension, bronchospasm, flushing, wheezing, stridor, urticaria, dyspnea, pyrexia, infusion-related reaction, face edema, edema mouth, periorbital edema, lip swelling, swollen tongue, tongue edema, lip edema, respiratory tract edema, chills, hypoxia, pruritus, rash, rash maculopapular, and rash erythematous occurring on the day of infusion or the day following an infusion.

[d]Fatigue includes fatigue and asthenia.

[e]Pyrexia not occurring on the day of infusion or the day following an infusion.

[f]Urticaria, not occurring on the day of infusion or the day following an infusion.

[g]Tachycardia includes sinus tachycardia and tachycardia.

[h]Peripheral neuropathy includes peripheral sensory neuropathy, peripheral motor neuropathy, paresthesia, and neuralgia.

[i]Neurological disorders of the eye includes unequal pupils, blurred vision, accommodation disorder, visual impairment, photophobia, and mydriasis.

Please see additional Important Safety Information throughout. Please see accompanying full Prescribing Information and Patient Information for DANYELZA including Boxed Warning on serious infusion-related reactions and neurotoxicity.

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DANYELZA® with GM-CSF: selected laboratory abnormalities observed (>20%) worsening from baseline[1]

Laboratory Abnormality	STUDY 201 N=25[a] All Grades %	STUDY 201 N=25[a] Grade 3 or 4 %	STUDY 12-230 N=72[b] All Grades %	STUDY 12-230 N=72[b] Grade 3 or 4 %
Chemistry				
Decreased potassium	63%	8%	47%	32%
Decreased albumin	50%	0%	68%	7%
Increased alanine aminotransferase	42%	8%	55%	9%
Decreased sodium	29%	0%	38%	6%
Increased glucose	N/A	N/A	74%	0%
Decreased calcium	N/A	N/A	64%	8%
Decreased magnesium	N/A	N/A	54%	0%
Increased aspartate aminotransferase	N/A	N/A	49%	4%
Decreased phosphate	N/A	N/A	47%	5%
Decreased glucose	N/A	N/A	29%	8%
Hematology				
Decreased lymphocytes	74%	30%	79%	56%
Decreased platelet count	65%	17%	71%	40%
Decreased neutrophils	61%	39%	72%	46%
Decreased hemoglobin	48%	4%	76%	42%

The table presents laboratory parameters with available grading according to Common Terminology Criteria for Adverse Events version 4.0. Baseline evaluation was the last non-missing value prior to first DANYELZA dosing. Each test incidence is based on the number of patients who had both a baseline value and at least 1 on-study laboratory measurement.

[a]Range: 23 to 24 patients.

[b]Range: 19 to 72 patients.

N/A=not applicable.

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DANYELZA® was studied in an outpatient setting, with a 60-minute first infusion[1,4*†‡]

Important administration information

DANYELZA is administered as an intravenous (IV) infusion after dilution at 3 mg/kg/day (up to 150 mg/day) on Days 1, 3, and 5 of each treatment cycle in combination with GM-CSF.

- Treatment cycles are repeated every 4 weeks until complete response or partial response, followed by 5 additional cycles every 4 weeks. Subsequent cycles may be repeated every 8 weeks. Discontinue DANYELZA and GM-CSF for disease progression or unacceptable toxicity
- For the first infusion (Cycle 1, Day 1), administer DANYELZA intravenously over 60 minutes. For subsequent infusions, administer over 30 to 60 minutes, as tolerated
- Do not administer DANYELZA as an IV push or bolus
- Administer GM-CSF at least 1 hour prior to DANYELZA administration
- If a DANYELZA dose is missed, administer the missed dose the following week by Day 10. Administer GM-CSF 500 μg/m^2/day on the first day of the DANYELZA infusion, and on the day before and on the day of the second and third infusion, respectively (i.e. a total of 5 days with 500 μg/m^2/day)

Administer preinfusion medications and supportive treatment, as appropriate, during infusion.

*Does not include premedication time and postinfusion observation.

†Infusion interruption or rate reduction may be used to manage serious infusion reactions and may impact total infusion time.

‡First infusion is cycle 1, Day 1.

IMPORTANT SAFETY INFORMATION

Serious Infusion-Related Reactions (cont'd)

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.

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Starting prior to infusion day[1]

Pain management

Beginning 5 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.

GM-CSF

GM-CSF is administered by subcutaneous injection beginning 5 days prior to the first infusion of DANYELZA in each cycle.

- On Days –4 to 0: administer GM-CSF 250 µg/m^2/day by subcutaneous injection
- On Days 1 to 5: administer GM-CSF 500 µg/m^2/day by subcutaneous injection
- Refer to the GM-CSF Prescribing Information for additional GM-CSF recommended dosing information

	PRESTART					START				
Day	–4	–3	–2	–1	0	1	2	3	4	5
Subcutaneous GM-CSF	250 µg/m^2/day					500 µg/m^2/day				
Intravenous DANYELZA						3 mg/kg/day		3 mg/kg/day		3 mg/kg/day

Preparing for Infusion

- Review information on infusion order
- Review notes from previous infusion if applicable
- Check for vital signs, including heart rate, respiratory rate, and blood pressure

IMPORTANT SAFETY INFORMATION

Serious Infusion-Related Reactions (cont'd)

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.

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Days of DANYELZA® infusion[1]

Premedication for infusion-related reactions and nausea/vomiting

In clinical studies, DANYELZA has been shown to cause serious infusion reactions, including cardiac arrest, anaphylaxis, hypotension, bronchospasm, and stridor.

Corticosteroids	Antihistamine, H2 antagonist, acetaminophen, and antiemetic
30–120 minutes prior to DANYELZA	30 minutes prior to DANYELZA
• For the first infusion: Administer IV corticosteroids (e.g. methylprednisolone 2 mg/kg with maximum dose of 80 mg or equivalent corticosteroid dose) prior to first DANYELZA infusion • Administer for subsequent infusions if a severe reaction occurred with the previous infusion or during the previous cycle	• Administer an antihistamine • Administer an H2 antagonist • Administer acetaminophen • Administer an antiemetic

Pain management

In clinical studies, DANYELZA has been shown to cause pain, including severe neuropathic pain. Pain typically began during the infusion and lasted for a median of less than 1 day (range less than 1 day and up to 62 days) in Study 201.

Opioids	Ketamine
45–60 minutes prior to DANYELZA	During infusion
• Administer oral opioids	• Consider use of ketamine for pain not adequately controlled by opioids
During infusion	
• Administer additional IV opioids as needed for breakthrough pain	

- 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

FLACC=Face, Legs, Activity, Cry, and Consolability; IV=intravenous.

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

Managing adverse reactions with DANYELZA® during infusion[1]

Dosage modifications for adverse 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.

- Reduce the rate of infusion, interrupt infusion, or permanently discontinue DANYELZA based on severity and institute appropriate medical management as needed. Please see *Table 2: Recommended DANYELZA Dosage Modifications for Adverse Reactions* in the full Prescribing Information
- 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
- Monitor patients closely for signs and symptoms of infusion-related reactions during and for at least 2 hours following completion of each DANYELZA infusion in a setting where cardiopulmonary resuscitation supportive medications and equipment are available

Supplies to keep 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.

IMPORTANT SAFETY INFORMATION

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.

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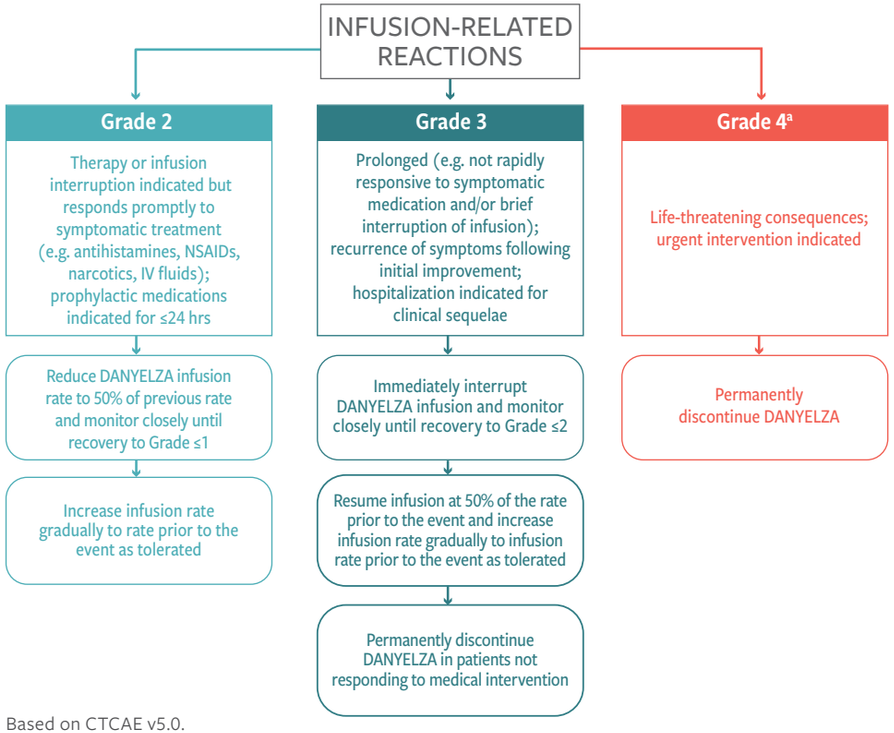
Recommended DANYELZA® dosage modifications for infusion-related reactions[1]

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.



Based on CTCAE v5.0.

[a]Includes Grade 3 or Grade 4 anaphylaxis.

CTCAE=Common Terminology Criteria for Adverse Events; IV=intravenous; NSAID=nonsteroidal anti-inflammatory drug.

IMPORTANT SAFETY INFORMATION

Transverse Myelitis

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

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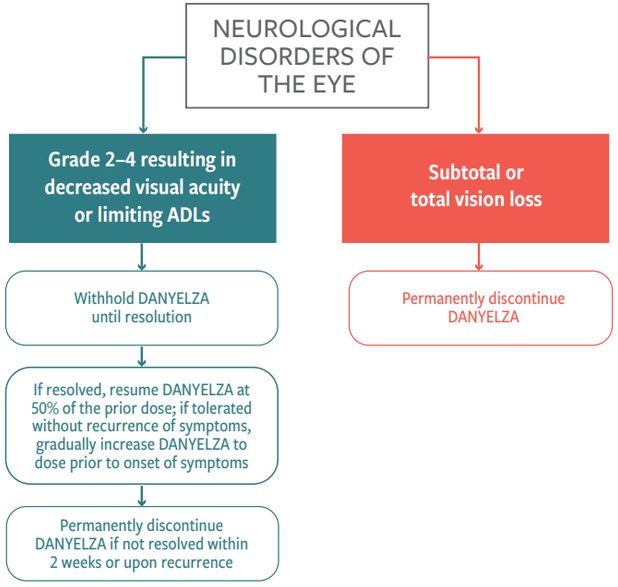
Recommended DANYELZA® dosage modifications for neurotoxicity[1]

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.



Based on CTCAE v5.0.

ADLs=activities of daily living; CTCAE=Common Terminology Criteria for Adverse Events.

Permanently discontinue DANYELZA® in cases of the following adverse reactions related to neurotoxicity[1]:

Pain: Grade 3 unresponsive to maximum supportive measures

- 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

Peripheral neuropathy: Grade ≥2 motor neuropathy or Grade 3 to 4 sensory 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

Prolonged urinary retention: persisting following discontinuation of opioids

- Urinary retention occurred in 1 (4%) patient in Study 201 and 3 patients (4%) in Study 12-230. All events in both studies occurred on the day of an infusion of DANYELZA

RPLS: All grades

- RPLS 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

Transverse myelitis: All grades

- Transverse myelitis has occurred with DANYELZA as reported in postmarketing experience/spontaneous reports

Based on CTCAE v5.0.

CTCAE=Common Terminology Criteria for Adverse Events; RPLS=reversible posterior leukoencephalopathy syndrome.

IMPORTANT SAFETY INFORMATION

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.

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IMPORTANT SAFETY INFORMATION

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.

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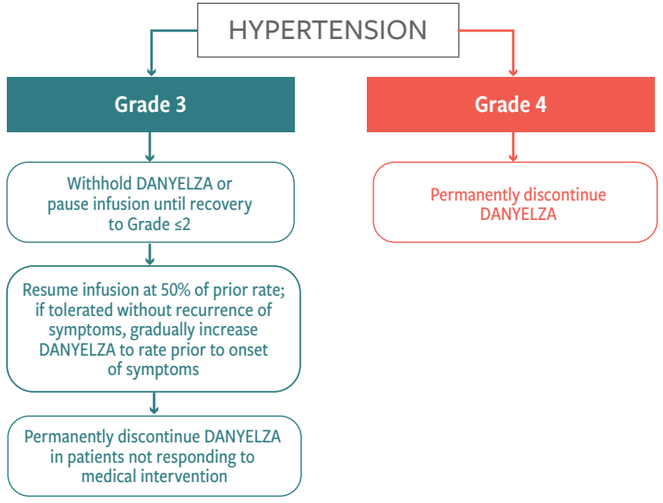
Recommended DANYELZA® dosage modifications for hypertension[1]

Hypertension occurred in 44% of patients in Study 201 and 28% of patients in Study 12-230. Do not initiate DANYELZA in patients with uncontrolled hypertension. Monitor blood pressure during infusion, and daily on Days 1 to 8 of each cycle and evaluate for complications of hypertension, including RPLS.

! Advise patients and caregivers that DANYELZA can cause hypertension and to immediately report signs or symptoms of hypertension.



Based on CTCAE v5.0.

CTCAE=Common Terminology Criteria for Adverse Events; RPLS=reversible posterior leukoencephalopathy syndrome.

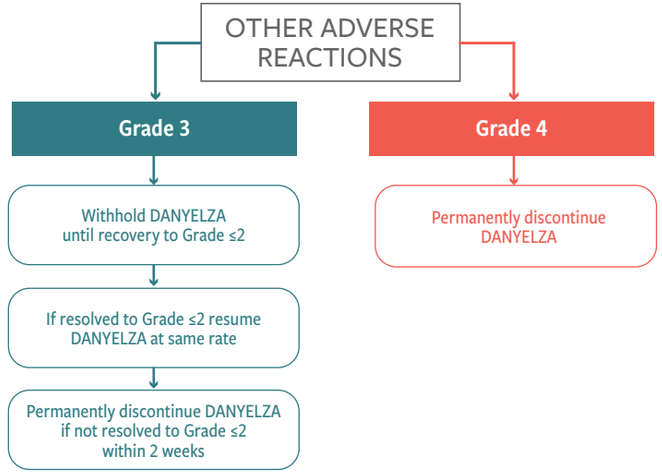
IMPORTANT SAFETY INFORMATION

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.

Please see additional Important Safety Information throughout. Please see accompanying full Prescribing Information and Patient Information for DANYELZA including Boxed Warning on serious infusion-related reactions and neurotoxicity.

Recommended DANYELZA® dosage modifications for other adverse reactions[1]



Based on CTCAE v5.0.

CTCAE=Common Terminology Criteria for Adverse Events.

IMPORTANT SAFETY INFORMATION

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.

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

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Postinfusion communications: Following DANYELZA® infusion, continue to closely monitor the patient for at least 2 hours in a setting where cardiopulmonary resuscitation medication and equipment are available[1]

- Document any pertinent information in the patient's chart (e.g. infusion rate changes, supportive measures)[1]
- Provide home instructions to the patient and caregiver, including when to call the physician[1]
- Set expectations for the next DANYELZA infusion and what follow-up will be necessary[1]

To report suspected adverse reactions, contact Y-mAbs Therapeutics, Inc. at **1-833-339-6227** (1-833-33YMABS), or the FDA at **1-800-FDA-1088** or **www.fda.gov/medwatch**

Access clinical resources, from training modules and videos to a variety of downloadable materials, on managing DANYELZA infusion-related reactions. Register for the Y-mabs Learning Program, an educational platform for oncology nurses, at **ymabslearning.com**

IMPORTANT SAFETY INFORMATION

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 see additional Important Safety Information inside. Please see accompanying full Prescribing Information and Patient Information for DANYELZA including Boxed Warning on serious infusion-related reactions and neurotoxicity.

References: 1. DANYELZA Prescribing Information. **2.** Cheung N-K V, Guo H, Hu J, Tassev DV, Cheung IY. Humanizing murine IgG3 anti-GD2 antibody m3F8 substantially improves antibody-dependent cell-mediated cytotoxicity while retaining targeting in vivo. *Oncoimmunology.* 2012;1(4):477-486. **3.** Harding FA, Stickler MM, Razo J, DuBridge R. The immunogenicity of humanized and fully human antibodies. *mAbs.* 2010;2(3):256-265. **4.** Data on file. Y-mAbs Therapeutics, Inc. **5.** Understanding cancer prognosis. National Cancer Institute website. Updated June 17, 2019. Accessed July 8, 2022. https://www.cancer.gov/about-cancer/diagnosis-staging/prognosis

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