


DANYELZA[®]
 (naxitamab-gqqk)
 40mg/10mL Injection

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.

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 throughout. Please see full [Prescribing Information](#) and Patient Information for DANYELZA including Boxed Warning on serious infusion-related reactions and neurotoxicity.

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 day¹

- 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/m²/day by subcutaneous injection (Day -4 through Day 0)

Day of infusion¹

GM-CSF

- Beginning Day 1 of the first infusion of DANYELZA in each cycle, administer GM-CSF at 500 µg/m²/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

- | | |
|---|--|
| <ul style="list-style-type: none"><input type="checkbox"/> 1. Corticosteroids
30 minutes to 2 hours prior to the first infusion of DANYELZA:<ul style="list-style-type: none">• 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 | <ul style="list-style-type: none"><input type="checkbox"/> 2. Antihistamine
30 minutes prior to each infusion<input type="checkbox"/> 3. H2 antagonist
30 minutes prior to each infusion<input type="checkbox"/> 4. Acetaminophen
30 minutes prior to each infusion<input type="checkbox"/> 5. Antiemetic
30 minutes prior to each infusion |
|---|--|

Pain Management

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

Supplies to have available during infusion*

- | | |
|---|--|
| <ul style="list-style-type: none">• Oxygen mask• Continuous pulse oximeter machine and probe• Nebulizer kits• Blood pressure machine/monitor | <ul style="list-style-type: none">• Emergency equipment• Cardiopulmonary resuscitation medication and equipment |
|---|--|

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

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 full [Prescribing Information](#) and Patient Information for DANYELZA including Boxed Warning on serious infusion-related reactions and neurotoxicity.


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Day of infusion¹ (cont)

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 below line)
- 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.

After infusion¹

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

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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.

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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-ggqk. 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.

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.

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Important Safety Information (cont)

WARNINGS AND PRECAUTIONS

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.

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.

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 ($\geq 25\%$ 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.

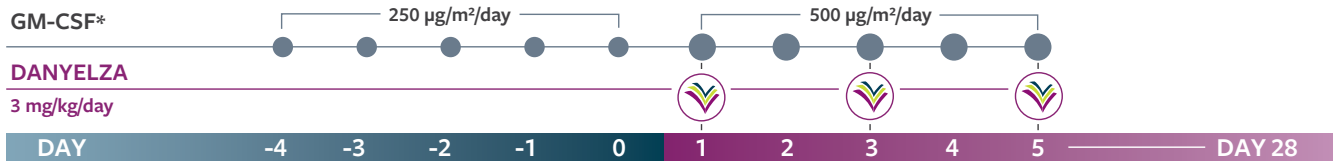
To review important state-specific disclosure information for licensed healthcare practitioners, please visit <https://www.ymabs.com/information-for-prescribers>

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

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DANYELZA with GM-CSF overview¹



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

DANYELZA with GM-CSF Treatment Course¹

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.



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Learn more at danyelzahcp.com

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