



08/2025

רופא/ה, רוקח/ת נכבד/ה,



## דניאלזה Danyelza

CONCENTRATE FOR SOLUTION FOR INFUSION

### עדכון העלון לרופא

חברת טקדה ישראל בע"מ מבקשת להודיעכם כי העלון לרופא של התכשיר שבנדון, בעקבות עדכון במשטר המינון, התעדכן באוגוסט 2025.

**התוויה המאושרת לתכשיר בישראל:**

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.

#### המרכיב הפעיל:

Naxitamab 4 mg/1 ml

שם היצרן: Y-MABS Therapeutics Inc., USA

בעל הרישום: טקדה ישראל בע"מ

להלן פירוט השינויים העיקריים בעלון לרופא (טקסט שנוסף מסומן באדום, טקסט שהושמט

מסומן כטקסט אדום עם קו חוצה, טקסט המהווה חמרה מודגש בצהוב):

### 2.3 Dosage Modifications for Adverse Reactions

The recommended dosage modifications for DANYELZA for adverse reactions are presented in Table 2.

Table 2. Recommended DANYELZA Dosage Modifications for Adverse Reactions

Adverse Reaction	Severity <sup>1</sup>	Dosage Modifications
...		
Myocarditis [see Warnings and Precautions (6.3)]	Grade 2 or 3	• Withhold, reduce dose, or permanently discontinue DANYELZA treatment based on severity and duration.
	Grade 4	• Permanently discontinue DANYELZA.
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Orthostatic hypotension <i>[see Warnings and precautions (6.5)]</i>	All grades	<ul style="list-style-type: none"><li>• Withhold DANYELZA until recovery to Grade <math>\leq</math> 1.</li><li>• If resolved within 1 week, restart DANYELZA at 50% of the prior dose; if tolerated without recurrence of symptoms after completion of next cycle, resume to recommended dose for subsequent cycles.</li><li>• If not resolved within 1 week, permanently discontinue DANYELZA.</li></ul>
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## 6 WARNINGS AND PRECAUTIONS

### 6.1 Serious Infusion-Related Reactions

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

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### 6.3 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 *[see Dosage and Administration (2.3) and Adverse Reactions (7.3)]*.

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### 6.5 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 *[see Dosage and Administration (2.3) and Adverse Reactions (7.3)]*.

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## 7 ADVERSE REACTIONS

The following clinically significant adverse reactions are also described elsewhere in the labeling:

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- Myocarditis *[see Warnings and Precautions (6.3)]*

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- Orthostatic Hypotension *[see Warnings and Precautions (6.5)]*

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### 7.3 Postmarketing Experience/Spontaneous Reports

The following adverse reactions have been identified during expanded access and post-approval use of



DANYELZA. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure.

Neurological: Orthostatic hypotension, Transverse myelitis

Cardiac disorders: Myocarditis

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העלון לרופא במתכונת עלון לצרכן של התכשיר שבנדון נשלח לפרסום לאתר משרד הבריאות.

למידע נוסף, יש לעיין במאגר התרופות שבאתר משרד הבריאות. כמו כן, ניתן לקבל העתק מודפס של העלונים באמצעות פנייה לבעל הרישום: טקדה ישראל בע"מ, רח' אפעל 25, פתח-תקווה, טל': 03-3733140.

בברכה,  
טקדה ישראל בע"מ