

08.12.2024

רופא/ה נכבד/ה
רוקח/ת נכבד/ה

הנדון:
טקוואילי 10TM מ"ג/מ"ל Tecvayli[®] 10mg/ml
טקוואילי 90TM מ"ג/מ"ל Tecvayli[®] 90mg/ml

חברת J-C Health Care Ltd מבקשת להודיעכם כי העלון לרופא של התכשיר שבנדון התעדכן **בדצמבר 2024**.
פרטי העדכון העיקריים מופיעים בהמשך (טקסט שנוסף מסומן באדום).

ההתוויות המאושרות לתכשיר בישראל:

TECVAYLI is indicated as monotherapy for the treatment of adult patients with relapsed and refractory multiple myeloma, who have received at least three prior therapies, including an immunomodulatory agent, a proteasome inhibitor, and an anti-CD38 antibody and have demonstrated disease progression on the last therapy.

מרכיב פעיל: Teclistamab 10mg/ml , Teclistamab 90mg/ml

העלונים המעודכנים נשלחו לפרסום במאגר התרופות שבאתר משרד הבריאות:
<https://israeldrugs.health.gov.il/#!/byDrug>

כמו כן, מצורפים לפרסום זה וניתן לקבל העתק מודפס שלהם באמצעות פנייה לבעל הרישום: J-C Health Care Ltd,
קיבוץ שפיים, 6099000, טל': 09-9591111.

בברכה,

יעל לפידות מללי
רוקחת ממונה
J-C Health Care Ltd

העדכון בעלון לרופא הינו:

4.2 Posology and method of administration

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Recommended dosing schedule

The recommended dosing schedule for TECVAYLI is provided in Table 1. The recommended doses of TECVAYLI are 1.5 mg/kg by subcutaneous injection (SC) weekly, preceded by step-up doses of 0.06 mg/kg and 0.3 mg/kg.

Treatment with TECVAYLI should be initiated according to the step-up dosing schedule in Table 1 to reduce the incidence and severity of cytokine release syndrome. Due to the risk of cytokine release syndrome, patients should be instructed to remain within proximity of a healthcare facility, and monitored for signs and symptoms daily for 48 hours after administration of all doses within the TECVAYLI step-up dosing schedule (see section 4.4).

Failure to follow the recommended doses or dosing schedule for initiation of therapy, or re-initiation of therapy after dose delays, may result in increased frequency and severity of adverse reactions related to mechanism of action, particularly cytokine release syndrome (see section 4.4).

Table 1: TECVAYLI dosing schedule

Dosing schedule	Day	Dose ^a	
Step-up dosing schedule ^b	Day 1	Step-up dose 1	0.06 mg/kg single dose
	Day 3 ^c	Step-up dose 2	0.3 mg/kg single dose
	Day 5 ^d	First maintenance dose	1.5 mg/kg single dose
Weekly dosing schedule ^b	One week after first maintenance dose and weekly thereafter ^e	Subsequent maintenance doses	1.5 mg/kg once weekly

^a Dose is based on actual body weight and should be administered subcutaneously.

^b See Table 2 for recommendations on restarting TECVAYLI after dose delays.

^c Step-up dose 2 may be given between two to seven days after Step-up dose 1..

^d First maintenance dose may be given between two to seven days after Step-up dose 2. This is the first full maintenance dose (1.5 mg/kg).^e Maintain a minimum of five days between weekly maintenance doses.

Refer to Tables 9, 10 and 11 to determine the dosage based on predetermined weight ranges (see section 6.6).

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