

02-2025

רופא/ה נכבד/ה
רוקח/ת נכבד/ה

הנדון:

Tecvayli® 10mg/ml טקוואילי™ 10 מ"ג/מ"ל
Tecvayli® 90mg/ml טקוואילי™ 90 מ"ג/מ"ל

חברת J-C Health Care Ltd מבקשת להודיעכם כי העלונים לרופא ולצרכן של התכשיר שבנדון התעדנו **בפברואר 2025**.

פרטי העדכון העיקריים מופיעים בהמשך (טקסט שנוסף מסומן באדום, טקסט שהושמט מסומן בטקסט **בחול עם קו-** **חוצה**, טקסט המהווה החמרה מודגש **ברקע צהוב**), אך קיימים עדכונים נוספים.

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

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4.2 Posology and method of administration

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Posology

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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. In patients who have a complete response or better for a minimum of 6 months, a reduced dosing frequency of 1.5 mg/kg SC every two weeks may be considered (see section 5.1).

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Table 1: TECVAYLI dosing schedule

Dosing schedule	Day	Dose ^a	
<u>All patients</u>			
Step-up dosing schedule^b	Day 1	Step-up dose 1	0.06 mg/kg <u>SC</u> single dose
	Day 3 ^c	Step-up dose 2	0.3 mg/kg <u>SC</u> single dose
	Day 5 ^d	First maintenance dose	1.5 mg/kg <u>SC</u> single dose
Weekly dosing schedule^b	One week after first maintenance dose and weekly thereafter ^c	Subsequent maintenance doses	1.5 mg/kg <u>SC</u> once weekly
<u>Patients who have a complete response or better for a minimum of 6 months</u>			
<u>Biweekly (every two weeks) dosing schedule^b</u>	<u>Consider reducing the dosing frequency to 1.5 mg/kg SC every two weeks</u>		

^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).^c 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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Restarting TECVAYLI after dose delay

If a dose of TECVAYLI is delayed, therapy should be restarted based on the recommendations listed in Table 2 and TECVAYLI resumed according to the dosing schedule (see Table 1). Pre-

treatment medicinal products should be administered as indicated in Table 2. Patients should be monitored accordingly (see section 4.2).

Table 2: Recommendations for restarting therapy with TECVAYLI after dose delay

Last dose administered	Duration of delay from the last dose administered	Action
Step-up dose 1	More than 7 days	Restart TECVAYLI step-up dosing schedule at Step-up dose 1 (0.06 mg/kg) ^a .
Step-up dose 2	8 days to 28 days	Repeat Step-up dose 2 (0.3 mg/kg) ^a and continue TECVAYLI step-up dosing schedule.
	More than 28 days	Restart TECVAYLI step-up dosing schedule at Step-up dose 1 (0.06 mg/kg) ^a .
Any maintenance doses	8 days to 28 days	Continue TECVAYLI dosing schedule at <u>last maintenance dose and schedule (1.5 mg/kg)^a</u> .
	More than 28 days	Restart TECVAYLI step-up dosing schedule at Step-up dose 1 (0.06 mg/kg) ^a .

^a Pre-treatment medicinal products should be administered prior to TECVAYLI dose and patients monitored accordingly.

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5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Clinical efficacy and safety

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Patients received initial step-up doses of 0.06 mg/kg and 0.3 mg/kg of TECVAYLI administered subcutaneously, followed by the maintenance dose of TECVAYLI 1.5 mg/kg, administered subcutaneously once weekly thereafter, until disease progression or unacceptable toxicity ([see section 4.2](#)). Patients who had a complete response (CR) or better for a minimum of 6 months were eligible to reduce dosing frequency to 1.5 mg/kg subcutaneously every two weeks until disease progression or unacceptable toxicity (see section 4.2). The median duration between Step-up Dose 1 and Step-up Dose 2 was 2.9 (Range: 2-7) days. The median duration between Step-up Dose 2 and the initial maintenance dose was 3.1 (Range: 2-9) days. Patients were hospitalised for monitoring for at least 48 hours after administration of each dose of the TECVAYLI Step-up dosing schedule.

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Results of an updated efficacy analysis after a median follow-up of 30.6 months among responders (n=104) showed a higher proportion of patients with CR (7.3%) and sCR (38.8%) compared with the primary analysis. MRD negativity rates also increased in all treated patients

(29.1%) and in patients achieving CR or sCR (51.3%). The median DOR was 24.0 (17.0, NE) months.

The median follow-up after schedule change was 12.6 (Range: 1.0 to 24.7) months in patients who switched to 1.5 mg/kg subcutaneously every two weeks.

5.2 Pharmacokinetic properties

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Elimination

Teclistamab clearance decreases over time, with a mean (CV%) maximal reduction from baseline to the 13th weekly maintenance dose of 40.8% (56%). The geometric mean (CV%) clearance is 0.472 L/day (64%) at the 13th weekly maintenance dose. Patients who discontinue teclistamab after the 13th weekly maintenance dose are expected to have a 50% reduction from C_{max} in teclistamab concentration at a median (5th to 95th percentile) time of 15 (7 to 33) days after T_{max} and a 97% reduction from C_{max} in teclistamab concentration at a median time of 69 (32 to 163) days after T_{max} .

Population pharmacokinetic analysis (based on MajesTEC-1) showed that soluble BCMA did not impact teclistamab serum concentrations.

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העדכון בעלון לצרכן הינו:

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3. כיצד תשתמש בתרופה?

יש להשתמש בתכשיר תמיד בהתאם להוראות הרופא. עליך לבדוק עם הרופא או הרוקח אם אינך בטוח בנוגע למינון ואופן הטיפול בתכשיר. המינון ואופן הטיפול יקבעו על ידי הרופא בלבד. המינון יהיה תלוי במשקל הגוף. שתי המנות הראשונות תהיינה נמוכות יותר. טקוואילי ניתן כדלהלן:

- תקבל 0.06 מ"ג לק"ג משקל גוף במנה הראשונה.
- תקבל 0.3 מ"ג לק"ג משקל גוף במנה השנייה כעבור 2-7 ימים.
- לאחר מכן תקבל מינון אחזקה של 1.5 מ"ג לק"ג משקל גוף 2-7 ימים לאחר המנה השנייה.
- לאחר מכן תמשיך לקבל מינון אחזקה פעם אחת בשבוע כל עוד אתה מפיק תועלת מטקוואילי.

אם אתה ממשיך להפיק תועלת מטקוואילי אחרי 6 חודשים, הרופא שלך עשוי להחליט שתקבל מינון אחזקה כל שבועיים.

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