TECVAYLI® ▼ 10mg/ml solution for injection and 90mg/ml solution for injection. **PRESCRIBING INFORMATION in United Kingdom (Great Britain)**

ACTIVE INGREDIENT(S): Teclistamab

Please refer to Summary of Product Characteristics (SmPC) before prescribing.

INDICATION(S):
Relapsed/Refractory multiple myeloma: as monotherapy for the treatment of adult patients 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.

DOSAGE & ADMINISTRATION: Adults: Initiated and supervised by physicians experienced in the treatment of multiple myeloma. **Pre-treatment medicinal products:** administer the following 1 to 3 hours prior to each dose of TECVAYLI in the step-up dosing schedule to reduce the risk of CRS (**cytokine release syndrome)**: Corticosteroid (oral or intravenous dexamethasone 16 mg), antihistamine (oral or intravenous diphenhydramine 50 mg, or equivalent) and antipyretics (oral or intravenous acetaminophen 650 to 1000 mg, or equivalent). Administration of pre-treatment medicinal products may also be required prior to administration of subsequent doses of TECVAYLI for some patients. Please refer to the SmPC for more details. **Recommended dosing schedule:** 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 of the SmPC). Initiate the treatment according to the step-up dosing schedule in Table 1 to reduce incidence and severity of cytokine release syndrome and continue until disease progression or unacceptable toxicity. Due to the risk of CRS, instruct patients to remain within proximity of a healthcare facility, and to be monitored for signs and symptoms daily for 48 hours after administration of all doses within the TECVAYLI step-up dosing schedule.

Table 1: TECVAYLI dosing schedule

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

[a] Dose is based on actual body weight and should be administered

subcutaneously. [b] Step-up dose 2 may be given between 2 to 7 days after

Step-up dose 1.

[c] First maintenance dose may be given between 2 to 7 days after Step-up dose 2. This is the first full treatment dose (1.5 mg/kg).

[d] Maintain a minimum of five days between weekly maintenance doses.

Children: The pharmacokinetics of TECVAYLI in paediatric patients aged 17 years and younger have not been investigated. **Elderly (65 years of age or older):** No dosage adjustment is required. **Renal impairment:** No dosage adjustment is recommended for patients with mild or moderate renal impairment. Limited data are available from patients with severe renal impairment. No formal studies of TECVAYLI in patients with renal impairment have been conducted. **Hepatic impairment:** No dosage adjustment is recommended for patients with mild hepatic impairment. No data are available in patients with moderate and severe hepatic impairment. No formal studies of TECVAYLI in patients with hepatic impairment have been conducted. Please see the SmPC for more details.

CONTRAINDICATIONS:
Refer to SmPC for hypersensitivity to the active substance or to any of the excipients.

SPECIAL WARNINGS & PRECAUTIONS:
CRS: life-threatening or fatal reactions may occur in patients receiving TECVAYLI. Treatment should be initiated with TECVAYLI according to the step-up dosing schedule to reduce risk of CRS. Pre-treatment medicinal products (corticosteroids, antihistamine, and antipyretics) should be administered prior to each dose of the TECVAYLI stepup dosing schedule. Patients who have received any dose within the TECVAYLI step-up dosing schedule, and patients who have received TECVAYLI after experiencing Grade 2 or higher CRS should remain within proximity of a healthcare facility and monitored daily for 48 hours. If CRS is suspected, TECVAYLI should be withheld until the adverse reaction resolves. Patients who experience CRS following their previous dose should be administered pre-treatment medicinal products prior to the next dose of TECVAYLI. Refer to the SmPC for the recommendations for management of CRS. **Neurotoxicities:** Serious or life-threatening neurologic toxicities, including Immune Effector Cell-Associated Neurotoxicity Syndrome (ICANS) occurred following treatment with TECVAYLI. Patients should be monitored for signs or symptoms of neurologic toxicities during treatment. At the first sign of neurologic toxicity, including ICANS, patients should be immediately evaluated and treated based on severity. Patients who experience Grade 2 or higher ICANS or first occurrence of Grade 3 ICANS with the previous dose of TECVAYLI should be instructed to remain within proximity of a healthcare facility and monitored for signs and symptoms daily for 48 hours. Refer to the SmPC for the recommendations for management of ICANS and other neurologic toxicities. **Infections:** Severe, life-threatening, or fatal infections have been reported in patients receiving TECVAYLI. Monitor patients for signs and symptoms of infection prior to and during treatment with TECVAYLI and treat appropriately. Prophylactic antimicrobials should be administered according to local institutional guidelines. Do not administer TECVAYLI step-up dosing schedule in patients with an active infection. **Hepatitis B virus reactivation:** Hepatitis B virus reactivation can occur in patients treated with medicinal products directed against B cells, and in some cases, may result in fulminant hepatitis, hepatic failure, and death. Monitor patients with evidence of positive HBV serology for clinical and laboratory signs of HBV reactivation while receiving TECVAYLI, and for at least six months following the end of TECVAYLI treatment. Refer to SmPC for full details. **Hypogammaglobulinaemia**: Monitor immunoglobulin levels during treatment with TECVAYLI. Patients should be treated according to local institutional guidelines, including infection

precautions, antibiotic or antiviral prophylaxis, and administration of immunoglobulin replacement. **Vaccines:** Immune response to vaccines may be reduced when taking TECVAYLI. Vaccination with live virus vaccines is not recommended for at least 4 weeks prior to the start of treatment, during treatment and least 4 weeks after treatment. **Neutropenia:** Monitor complete blood cell counts at baseline and periodically during treatment. Supportive care should be provided per local institutional guidelines. Patients with neutropenia should be monitored for signs of infection. Refer to the SmPC for full details.

SIDE EFFECTS:
Refer to SmPC for full details on side effects.
Very common: Pneumonia, COVID-19, upper respiratory tract infection, neutropenia, thrombocytopenia, lymphopenia, anaemia, leukopenia, CRS, hypogammaglobulinemia, hypercalcaemia, hypokalaemia, hypophosphataemia, hypomagnesaemia, decreased appetite, peripheral neuropathy, headache, haemorrhage, hypertension, dyspnoea, cough, diarrhoea, vomiting, nausea, constipation, musculoskeletal pain, pyrexia, injection site reaction, pain, oedema, fatigue, increased blood alkaline phosphatase. **Common:** sepsis, cellulitis, febrile neutropenia, hypofibrinogenaemia, hyperamylasaemia, hyperkalaemia, hyponatraemia, hypocalcaemia, hypoalbuminaemia, ICANS, encephalopathy, hypoxia, increased blood creatinine, transaminase elevation, increased lipase, increased gamma-glutamyltransferase, prolonged activated partial thromboplastin time, increased international normalised ratio.

Serious adverse reactions: *Cytokine Release Syndrome*: In MajesTEC-1 (N=165), CRS was reported in 72% of patients following treatment with TECVAYLI. One-third (33%) of patients experienced more than one CRS event. CRS events were Grade 1 (50%) and Grade 2 (21%) or Grade 3 (0.6%). *Neurologic toxicities:* In MajesTEC-1 (N=165), neurologic toxicity events were reported in 15% of patients receiving TECVAYLI. Neurologic toxicity events were Grade 1 (8.5%), Grade 2 (5.5%), or Grade 4 (<1%).

Refer to the SmPC for other side effects.

WOMEN OF CHILD-BEARING POTENTIAL/CONTRACEPTION IN MALES AND FEMALES: Women of child-
bearing potential should use effective contraception during treatment and for five months after the final dose of TECVAYLI. In clinical studies, male patients with a female partner of child-bearing potential used effective contraception during treatment and for three months after the last dose of TECVAYLI.

PREGNANCY: There are no available data on the use of teclistamab in pregnant women or animal data to assess the risk of teclistamab in pregnancy. TECVAYLI is not recommended for women who are pregnant.

BREAST-FEEDING: Patients should be advised not to breast feed during treatment with TECVAYLI and for at least five months after the last dose.

INTERACTIONS:
No interaction studies have been performed with TECVAYLI. The initial release of cytokines associated with the start of TECVAYLI treatment could suppress CYP450 enzymes. The highest risk of interaction is expected to be from initiation of TECVAYLI step-up schedule up to 7 days after the first maintenance dose or during a CRS event. During this time period, toxicity or medicinal product concentrations (e.g., cyclosporine) should be monitored in patients who are receiving concomitant CYP450 substrates with a narrow therapeutic index. The dose of the concomitant medicinal product should be adjusted as needed. See SmPC for full details.

LEGAL CLASSIFICATION: Prescription Only Medicine (POM)

PRESENTATIONS, PACK SIZES, MARKETING AUTHORISATION NUMBER(S) & BASIC NHS COSTS

PRESENTATIONS	PACK SIZES	MARKETING AUTHORISATION NUMBER(S)	BASIC NHS COSTS
10 mg/mL solution for injection (30mg of teclistamab)	1 vial	PLGB 00242/0751 EU/1/22/1675/001	£775.14
90 mg/mL solution for injection (153mg of teclistamab)	1 vial	PLGB 00242/0752 EU/1/22/1675/002	£3,952.78

MARKETING AUTHORISATION HOLDER:
Great Britain (PLGB): Janssen-Cilag Limited, 50-100 Holmers Farm Way, High Wycombe, Buckinghamshire, HP12 4EG UK.

Northern Ireland (EU): Janssen-Cilag International NV Turnhoutseweg 30, B-2340 Beerse, Belgium

FURTHER INFORMATION IS AVAILABLE FROM: Janssen-Cilag Limited, 50-100 Holmers Farm Way, High Wycombe, Buckinghamshire, HP12 4EG UK.

Prescribing information last revised: December 2023

Adverse events should be reported. ▼ This medicinal product is subject to additional monitoring, and it is therefore important to report any suspected adverse events related to this medicinal product. Reporting forms and information can be found at https://yellowcard.mhra.gov.uk/ or search for MHRA Yellow Card in the Google Play or Apple App Store. Adverse events should also be reported to Janssen-Cilag Limited on 01494 567447 or at dsafety@its.jnj.com.

TECVAYLI® ▼ 10mg/ml solution for injection and 90mg/ml solution for injection. **PRESCRIBING INFORMATION in United Kingdom (Northern Ireland)**

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Table 1: TECVAYLI dosing schedule

<table>
<tr><td colspan="4">All patients</td></tr>
<tr><td>Dosing schedule</td><td>Day</td><td colspan="2">Dose[a]</td></tr>
<tr><td rowspan="3">Step-up dosing schedule</td><td>Day 1</td><td>Step-up dose 1</td><td>0.06 mg/kg SC single dose</td></tr>
<tr><td>Day 3[b]</td><td>Step-up dose 2</td><td>0.3 mg/kg SC single dose</td></tr>
<tr><td>Day 5[c]</td><td>First maintenance dose</td><td>1.5 mg/kg SC single dose</td></tr>
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<tr><td>Biweekly (every two weeks) dosing schedule</td><td colspan="3">Consider reducing the dosing frequency to 1.5 mg/kg SC every two weeks</td></tr>
</table>

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

[b] Step-up dose 2 may be given between 2 to 7 days after Step-up dose 1.

[c] First maintenance dose may be given between 2 to 7 days after Step-up dose 2. This is the first full treatment dose (1.5 mg/kg).

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ADVERSE EVENTS:
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Serious adverse reactions: *Cytokine Release Syndrome*: In MajesTEC-1 (N=165), CRS was reported in 72% of patients following treatment with TECVAYLI. One-third (33%) of patients experienced more than one CRS event. CRS events were Grade 1 (50%) and Grade 2 (21%) or Grade 3 (0.6%). *Neurologic toxicities:* In MajesTEC-1 (N=165), neurologic toxicity events were reported in 15% of patients receiving TECVAYLI. Neurologic toxicity events were Grade 1 (8.5%), Grade 2 (5.5%), or Grade 4 (<1%).

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PREGNANCY: There are no available data on the use of teclistamab in pregnant women or animal data to assess the risk of teclistamab in pregnancy. TECVAYLI is not recommended for women who are pregnant.

BREAST-FEEDING: Patients should be advised not to breast feed during treatment with TECVAYLI and for at least five months after the last dose.

INTERACTIONS:
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LEGAL CLASSIFICATION: Prescription Only Medicine (POM)

PRESENTATIONS, PACK SIZES, MARKETING AUTHORISATION NUMBER(S) & BASIC NHS COSTS

PRESENTATIONS	PACK SIZES	MARKETING AUTHORISATION NUMBER(S)	BASIC NHS COSTS
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	1 vial	PLGB 00242/0752	£3,952.78

90 mg/mL solution for injection (153mg of teclistamab)		EU/1/22/1675/002	

MARKETING AUTHORISATION HOLDER:
Great Britain (PLGB): Janssen-Cilag Limited, 50-100 Holmers Farm Way, High Wycombe, Buckinghamshire, HP12 4EG UK.

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Prescribing information last revised: June 2024

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