▼TECVAYLI™ 10 mg/mL and 90 mg/mL solution for injection
ABBREVIATED PRESCRIBING INFORMATION

ACTIVE INGREDIENT(S): Teclistamab

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

INDICATION(S): 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.

DOSAGE & ADMINISTRATION: TECVAYLI should be administered by a healthcare professional with adequately trained medical personnel and appropriate medical equipment to manage severe reactions, including cytokine release syndrome (CRS). Treatment should be initiated according to the step-up dosing schedule (Table 1 of the SmPC) to reduce the incidence and severity of CRS. Patients should be instructed to remain within proximity of a healthcare facility and monitored for signs and symptoms of CRS daily for 48 hours after administration of all step up doses. TECVAYLI step-up dosing schedule should not be administered in patients with active infection. The recommended subcutaneous dose on day 1 is 0.06 mg/kg (Step-up dose 1). On day 3, it is 0.3 mg/kg (Step-up dose 2). On day 5, it is 1.5 mg/kg (first maintenance/full treatment dose). Doses in step up dose schedule can be given as early as 2 days after last dose or as late as 7 days after last dose. For doses that cannot be given within 7 days please see below. One week after the first maintenance dose, patients may begin weekly maintenance dosing of 1.5mg/kg. Maintain a minimum of five days between weekly maintenance doses. 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. ***Duration of treatment:*** It is recommended that patients should be treated with TECVAYLI until disease progression or unacceptable toxicity. ***Pre-treatment medicinal products:*** Corticosteroid, Antihistamine, Antipyretics must be administered 1 to 3 hours before each dose of the TECVAYLI step-up dosing schedule to reduce the risk of CRS. **For detailed premedication administration instructions, please refer to SmPC.** ***Prevention of herpes zoster reactivation****:* Prior to starting treatment with TECVAYLI, antiviral prophylaxis should be considered for the prevention of herpes zoster virus reactivation.
Dose modifications**:** Dose reductions are not recommended. Dose delays may be required to manage toxicities related to TECVAYLI. ***Restarting TECVAYLI after dose delay:*** If the duration of delay for Step-up dose 1 (from last dose administered) is more than 1 week (> 7 days), restart TECVAYLI step-up dosing schedule at 0.06 mg/kg. If the duration of delay for Step-up dose 2 (from last dose administered) is more than 1 week to less than or equal to 4 weeks (8 days to ≤ 28 days), repeat 0.3 mg/kg and continue step-up dosing schedule; if it is more than 4 weeks (> 28 days), restart step-up dosing schedule at 0.06 mg/kg. If the duration of delay for any maintenance doses (from last dose administered) is more than 1 week to less than or equal to 9 weeks (8 days to ≤ 63 days), continue TECVAYLI dosing schedule at 1.5 mg/kg once weekly/every two weeks; if it is more than 9 weeks to less than or equal to 16 weeks (64 to ≤ 112 days) restart step-up dosing schedule at 0.3 mg/kg; if it is more than 16 weeks (> 112 days), restart step-up dosing schedule at 0.06 mg/kg. ***Refer to the SmPC for recommended actions taken after adverse reactions following administration of TECVAYLI****.*
Children: No relevant use in the paediatric population.
Elderly: No dosage adjustment is necessary.
Renal impairment: No dosage adjustment is recommended for patients with mild or moderate renal impairment.
Hepatic impairment: No dosage adjustment is recommended for patients with mild hepatic impairment.

CONTRAINDICATIONS: Hypersensitivity to the active substance or to any of the excipients (see SmPC).

SPECIAL WARNINGS & PRECAUTIONS:
Please refer to SmPC for information on the following special warnings and precautions: Traceability*;* Cytokine release syndrome (CRS)*;* Neurologic toxicities, including ICANS*;* Infections*;* Hepatitis B virus reactivation*;* Hypogammaglobulinaemia; Vaccines; Neutropenia, Excipients.

SIDE EFFECTS: Very Common: Pneumonia, COVID-19, Upper respiratory tract infection, Urinary tract infection, Neutropenia, Thrombocytopenia, Lymphopenia, Anaemia, Leukopenia, CRS, Hypogammaglobulinaemia, Hypercalcaemia, Hypokalaemia, Hypophosphataemia, Hypomagnesaemia, Decreased appetite, Neuropathy

peripheral, Headache, Hemorrhage, Hypertension, Hypotension, Dyspnoea, Cough, Diarrhoea, Abdominal pain, Vomiting, Nausea, Constipation, Musculoskeletal pain, Muscle spasms, Pyrexia, Injection site reaction, Pain, Oedema, Fatigue, Blood alkaline phosphatase increased; **Common**: Sepsis, Cellulitis, Febrile Neutropenia, Hypofibrinogenaemia, Hyperamylasaemia, Hyperkalaemia, Hyponatraemia, Hypocalcaemia, Hypoalbuminaemia, Hypoglycaemia, Immune effector cell-associated neurotoxicity syndrome (ICANS), Encephalopathy, Hypoxia, Blood creatinine increased, Transaminase elevation, Lipase increased, Gamma-glutamyltransferase increased, Activated partial thromboplastin time prolonged, International normalised ratio increased; **Uncommon:** Progressive multifocal leukoencephalopathy.

Refer to the SmPC for further information on side effects.

LEGAL CATEGORY: Prescription Only Medicine

PRESENTATIONS, PACK SIZES, MARKETING AUTHORISATION NUMBER(S):

10 mg/mL solution for injection, EU/1/22/1675/001.

90 mg/mL solution for injection, EU/1/22/1675/002.

MARKETING AUTHORISATION HOLDER: Janssen-Cilag International NV, Turnhoutseweg 30, B-2340 Beerse Belgium.

FURTHER INFORMATION IS AVAILABLE FROM: Janssen Sciences Ireland UC, Barnahely, Ringaskiddy, IRL – Co. Cork P43 FA46

Prescribing information updated: July 2025.

Adverse events should be reported. ▼This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse reactions via: HPRA Pharmacovigilance, Website: www.hpra.ie. Adverse events should also be reported to Janssen Sciences Ireland UC, a Johnson & Johnson Company, on 0044 1494 567447 or at dsafety@its.jnj.com.