TALVEY®▼ 2 mg/mL and 40 mg/mL solution for injection
ABBREVIATED PRESCRIBING INFORMATION

ACTIVE INGREDIENT(S): talquetamab

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

INDICATION(S):
TALVEY is indicated as monotherapy for the treatment of adult patients with relapsed and refractory multiple myeloma, who have received at least 3 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:
Treatment with TALVEY 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) and neurologic toxicity, including immune effector cell-associated neurotoxicity syndrome (ICANS). **Posology**: Treatment with TALVEY should be initiated according to the step-up dosing schedule (Table 1 of the SmPC) to reduce the incidence and severity of CRS. TALVEY should be given subcutaneously on a weekly or biweekly (every 2 weeks) dosing schedule. The weekly recommended subcutaneous dose on day 1 is 0.01 mg/kg, on day 3, it is 0.06 mg/kg and on day 5, it is 0.4 mg/kg, followed by a treatment dose of 0.4 mg/kg once a week thereafter. The biweekly dosing schedule on day 1 is 0.01 mg/kg, on day 3 is 0.06 mg/kg, on day 5 is 0.4 mg/kg, and on day 7 is 0.8 mg/kg, followed by a treatment dose of 0.8 mg/kg once every 2 weeks thereafter. Patients who receive talquetamab according to the 0.4 mg/kg weekly dosing schedule and have attained an adequate clinical response that is confirmed in at least two consecutive disease assessments can be considered for switch to the 0.8 mg/kg biweekly dosing schedule. Patients should be instructed to remain within proximity of a healthcare facility and monitored for 48 hours after administration of all doses within the TALVEY step-up phase for signs and symptoms of CRS and ICANS. **Duration of treatment:** Patients should be treated with TALVEY until disease progression or unacceptable toxicity. **Pre-treatment medicinal products:** Corticosteroid, Antihistamine, Antipyretics must be administered 1 to 3 hours before each dose of TALVEY step-up dosing schedule to reduce the risk of CRS. *For detailed premedication administration instructions, please refer to SmPC*. **Prevention of infection***:* Prior to starting treatment with TALVEY, prophylaxis should be considered for the prevention of infections, per local institutional guidelines. **Dose delays:** Therapy should be restarted based on recommendations in Table 2 of the SmPC, and weekly or biweekly dosing should be resumed accordingly if a dose of TALVEY is delayed. Refer to Tables 3, 4, 5 and 6 of the SmPC for recommended dose modifications for adverse reactions following administration of TALVEY. **Paediatric population:** No relevant use of TALVEY in the paediatric population. **Elderly:** No dose adjustment is required. **Renal impairment:** No dose adjustment for patients with mild or moderate renal impairment. **Hepatic impairment:** No dose adjustment for patients with mild hepatic impairment. Limited or no data are available in patients with moderate and severe 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 toxicity, including ICANS, Oral toxicity, Serious infections, Hypogammaglobulinaemia, Cytopenias, Skin reactions, Vaccines, Women of child-bearing potential/contraception, Excipients.

SIDE EFFECTS: Very Common: Bacterial infection, fungal infection, COVID-19, Upper respiratory tract infection, Neutropenia, Anaemia, Thrombocytopenia, Lymphopenia, Leukopenia, Cytokine release syndrome, Hypogammaglobulinaemia, Decreased appetite, Hypokalaemia, Hypophosphataemia, Hypomagnesaemia, Immune effector cell-associated neurotoxicity syndrome, Encephalopathy, Headache, Motor dysfunction,

Dizziness, Sensory neuropathy, Cough, Dyspnoea, Dysgeusia, Dry mouth, Dysphagia, Diarrhoea, Stomatitis, Nausea, Constipation, Oral pain, Abdominal pain, Vomiting, Rash, Skin disorder, Xerosis, Pruritis, Nail disorder, Musculoskeletal pain, Fatigue, Weight decreased, Pyrexia, Pain, Oedema, Injection site reaction, Chills, Fibrinogen decreased, aPTT prolonged, Transaminase elevation, INR increased, Gamma-glutamyltransferase increased. **Common:** Sepsis, Pneumonia, Viral infection, Haemorrhage, Febrile neutropenia, Palmar-plantar erythrodysesthesia syndrome, Alopecia. **Uncommon:** Ataxia.

Refer to SmPC for further information on side effects.

LEGAL CATEGORY: Prescription Only Medicine (POM)

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

PRESENTATIONS	PACK SIZES	MARKETING AUTHORISATION NUMBER(S)
2 mg/mL solution for injection	1 vial	EU/1/23/1748/001
40 mg/mL solution for injection	1 vial	EU/1/23/1748/002

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: October 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.