Abbreviated Prescribing Information (EU APR21-HK JUN21)

Ninlaro 2.3mg, 3mg and 4mg Capsules

Active Ingredient: Ixazomib citrate Indication: NINLARO in combination with lenalidomide and dexamethasone is indicated for the treatment of adult patients with multiple myeloma who have received at least one prior therapy.

Dose & Administration: The recommended starting dose of NINLARO is 4 mg administered orally once a week on Days 1, 8, and 15 of a 28-day treatment cycle. The recommended starting dose of lenalidomide is 25 mg administered daily on Days 1 to 21 of a 28-day treatment cycle. The recommended starting dose of dexamethasone is 40 mg administered on Days 1, 8, 15, and 22 of a 28-day treatment cycle. Treatment should be continued until disease progression or unacceptable toxicity. Ninlaro 3mg and 2.3mg are available for dose modification according to the dose modifications guidelines. NINLARO is for oral use. NINLARO should be taken at approximately the same time on days 1, 8, and 15 of each treatment cycle at least 1 hour before or at least 2 hours after food. The capsule should be swallowed whole with water. It should not be crushed, chewed, or opened.

Contraindications: Hypersensitivity to ixazomib citrate.

Special precautions: Thrombocytopenia has been reported with NINLARO with platelet nadirs typically occurring between Days 14-21 of each 28-day cycle and recovery to baseline by the start of the next cycle. Diarrhoea, constipation, nausea and vomiting have been reported with NINLARO, occasionally requiring use of antiemetic and antidiarrhoeal medicinal products and supportive care. The dose should be adjusted for severe (Grade 3-4) symptoms. In case of severe gastrointestinal events, monitoring of serum potassium level is recommended. Patients experiencing new or worsening peripheral neuropathy may require dose modification. Rash should be managed with supportive care or with dose modification if Grade 2 or higher. Cases of thrombotic microangiopathy, including thrombotic thrombocytopenic purpura, have been reported in patients who received NINLARO, some of these events have been fatal, signs and symptoms of thrombotic microangiopathy should be monitored. Women should avoid becoming pregnant while being treated with NINLARO. Women of childbearing potential must use highly effective contraception while taking NINLARO and for 90 days after stopping treatment. Women using hormonal contraceptives should additionally use a barrier method of contraception.

Adverse Reactions: upper respiratory tract infection, thrombocytopenia, neutropenia, peripheral neuropathy, diarrhoea, nausea, vomiting, constipation, rash, peripheral oedema.

For details, please refer to full prescribing information.

For reporting suspected side effects for Takeda products at AE.HongKong@takeda.com

For asking medical information and other inquiries for Takeda products at medinfoHK@takeda.com