Abbreviated Prescribing Information (EU-DEC21-HK-FEB22)

Ninlaro 2.3mg, 3mg and 4mg Capsules

Presentation: Ixazomib 2.3 mg, 3 mg and 4 mg gelatin hard capsules. **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. **Dosage and administration:** Recommended starting doses: NINLARO 4 mg (one capsule) administered orally once a week on Days 1, 8, and 15 of a 28-day treatment cycle at least 1 hour before or at least 2 hours after food; lenalidomide 25 mg administered daily on Days 1 to 21 of a 28-day treatment cycle; dexamethasone 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. Treatment with NINLARO in combination with lenalidomide and dexamethasone for longer than 24 cycles should be based on an individual benefit risk assessment, as the data on the tolerability and toxicity beyond 24 cycles are limited. Antiviral prophylaxis should be considered in patients being treated with NINLARO to decrease the risk of herpes zoster reactivation. No dose adjustment is necessary in patients over 65 years of age. Reduced 3 mg starting dose recommended in moderate or severe hepatic impairment. Reduced 3 mg starting dose recommended in severe renal impairment or end-stage renal disease requiring dialysis. **Contraindications:** Hypersensitivity to the active substance or to its excipients. As NINLARO is administered in combination with lenalidomide and dexamethasone, refer to the package insert for these medicinal products for additional contraindications. **Warnings and 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. Platelet counts should be monitored at least monthly during NINLARO treatment. Thrombocytopenia can be managed with dose modifications and platelet transfusions as per standard medical guidelines. 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. Patients experiencing new or worsening peripheral neuropathy may require dose modification. Patients with peripheral oedema should be evaluated for underlying causes and provided supportive care, as necessary. The dose of dexamethasone should be adjusted per its package insert or NINLARO for Grade 3 or 4 symptoms. Rash should be managed with supportive care or with dose modification if Grade 2 or higher. Stevens-Johnson syndrome (SJS) has also been reported with NINLARO. If SJS occurs, discontinue NINLARO. Cases of Thrombotic microangiopathy (TMA), including thrombotic thrombocytopenic purpura (TTP) have been reported in patients who received NINLARO. Some of these have been fatal. Signs and symptoms of TMA should be monitored for and NINLARO stopped if diagnosis is suspected. Hepatic enzymes should be monitored regularly and dose should be adjusted for Grade 3 or 4 symptoms. Pregnancy: Women should avoid becoming pregnant while being treated with NINLARO. In patients developing Posterior reversible encephalopathy syndrome (PRES), discontinue NINLARO. **Interactions:** Co-administration of strong CYP3A inducers with NINLARO is not recommended. No dose modification is required for NINLARO with co-administration of strong CYP3A inhibitors or strong CYP1A2 inhibitors. Women should avoid becoming pregnant while being treated with NINLARO. Male and female patients of childbearing potential must use effective contraceptive measures during and for 90 days following treatment. Women using oral hormonal contraceptives should additionally use a barrier method of contraception. Breast feeding should be discontinued. **Undesirable effects:** Very common (all grades): Upper respiratory tract infection, bronchitis, thrombocytopenia, neutropenia, peripheral neuropathies, diarrhoea, constipation, nausea, vomiting, rash, back pain, oedema peripheral. Common (all grades): Herpes zoster. Serious adverse reactions: Serious adverse reactions reported in ≥2% of patients included diarrhoea (3%), thrombocytopenia (2%) and bronchitis (2%).
As Ixazomib is administered in combination with lenalidomide and dexamethasone, refer to the package insert for these medicinal products for additional undesirable effects.

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