SFDA

Safety Communication

[10/05/2022]

Potential Risk of Multiple Myeloma with Teriparatide Use

The Saudi Food & Drug Authority (SFDA) would like to notify healthcare professionals about the potential risk of multiple myeloma associated with teriparatide use.

Teriparatide (Forteo®) is a recombinant human parathyroid hormone. It is approved by the SFDA in 2018 for the treatment of osteoporosis in postmenopausal women and men at increased risk of fracture and for treatment of men and women with osteoporosis associated with sustained systemic glucocorticoid therapy at high risk for fracture.

Multiple myeloma is a neoplastic proliferation of plasma cells producing a monoclonal immunoglobulin, which results in extensive skeletal destruction with osteolytic lesions, osteopenia, and/or pathologic fractures. Monoclonal gammopathy of undetermined significance (MGUS) is characterized by the presence of a monoclonal paraprotein in the blood, without the characteristic end organ damage seen in multiple myeloma. Risk factors for a patient with MGUS to progress to multiple myeloma or related malignancies include younger age, size of the M protein when diagnosed, abnormal serum free light chain ration, more than 5% bone marrow plasma cells, presence of IgM or IgA M protein, presence of Bence Jones proteinuria, polyclonal immunoglobulin reduction, and elevated sedimentation rate.

We reviewed published literature and post marketing databases on the potential risk of multiple myeloma using of teriparatide. Our review found three published case-reports of osteoporosis patients, known to have MGUS before starting teriparatide, who developed MM with the use of teriparatide treatment. In addition, we identified 203 spontaneous case reports of multiple myeloma with teriparatide use in the World Health Organization (WHO) database reported between 1999 and April 2022. The cases included 162 females (79.8%), 40 males (19.7%), and gender unknown in single case. The age range in most cases between 9 to 91 years. Most of cases reported were from the United States. Time of onset in most cases ranged from 3 months to 4 years following teriparatide use.

Therefore, the SFDA requests to update the product information to emphasize that teriparatide in contraindicated in patients with multiple myeloma. Also, if a patient has MGUS with a likelihood of progression to multiple myeloma, the physician should consider not prescribing teriparatide unless the potential benefits of medication outweigh any potential risks.

Call for reporting:

The SFDA urges both healthcare professionals and patients to report ADRs related to use of any medication to the SFDA using the following contact information:

The National Pharmacovigilance Centre (NPC):
Fax: +966-11-205-7662
SFDA Call Center: 19999
E-mail: npc.drug@sfda.gov.sa
Website: https://ade.sfda.gov.sa