# Safety Alert Dec 2023

## Alendronate - Risk of low-energy fractures observed in bones other than the femur

**EDA performs label update to include the following:**

**WARNINGS AND PRECAUTIONS**

**Musculoskeletal**
Atypical fractures: **Low-energy fractures of the subtrochanteric and proximal femoral shaft and other bones have been reported in some long-term** (time to onset in the majority of reports ranged from 18 months to 10 years) alendronate-treated patients. Some were stress fractures (some of which were reported as insufficiency fractures) occurring in the absence of apparent trauma or **induced by mild external force.**

**8 ADVERSE REACTIONS**
Post-Market Adverse Reactions

Musculoskeletal: bone, joint, and/or muscle pain, occasionally severe and/or incapacitating; joint swelling; **low-energy fractures of the femoral shaft and other bones**

**Background:**
**Atypical fracture:**
Atypical femoral fracture is **an uncommon complication of long-term use of bisphosphonates**. Atypical femoral fractures are stress or insufficency fractures occurring in the femoral shaft. Prodomal thigh or groin pain may occur before fracture.

***References:***

***Health Canada*** *(Click here)*