

TYPE: Drug Safety Communication

New Information on Bone Fracture Risk and Decreased Bone Mineral Density

Drug Name: **Invokana and Invokamet (canagliflozin)**

Audience: Endocrinology, Nursing, Family Practice

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ISSUE

FDA has strengthened the warning for the type 2 diabetes medicine **canagliflozin (Invokana, Invokamet)** related to the increased risk of bone fractures, and added new information about decreased bone mineral density. To address these safety concerns, FDA added a new WARNING AND PRECAUTION and revised the ADVERSE REACTIONS section of the Invokana and Invokamet drug labels.

FDA is continuing to evaluate the risk of bone fractures with other drugs in the SGLT2 inhibitor class, including dapagliflozin (Farxiga, Xigduo XR) and empagliflozin (Jardiance, Glyxambi, Synjardy), to determine if additional label changes or studies are needed. Health care professionals and patients are urged to report side effects involving canagliflozin or other SGLT2 inhibitors to the FDA MedWatch program.

BACKGROUND

Canagliflozin is a prescription medicine used with diet and exercise to lower blood sugar in adults with type 2 diabetes. It belongs to a class of drugs called sodium-glucose cotransporter-2 (SGLT2) inhibitors. Canagliflozin is available as a single-ingredient product under the brand name Invokana and also in combination with the diabetes medicine metformin under the brand name Invokamet. Bone mineral density relates to the strength of a person's bones.

RECOMMENDATION

Health care professionals should consider factors that contribute to fracture risk prior to starting patients on canagliflozin. Patients should talk to their health care professionals about factors that may increase their risk for bone fracture. Patients should not stop or change their diabetes medicines without first talking to their health care professional. *Additional information for Health Care Professionals:*

- Bone fractures have been seen in patients taking the type 2 diabetes medicine canagliflozin.
- Fractures can occur as early as 12 weeks after starting canagliflozin.
- Canagliflozin has also been linked to decreases in bone mineral density at the hip and lower spine.
- Consider factors that contribute to fracture risk prior to initiating canagliflozin.
- Counsel patients about factors that may contribute to bone fracture risk.

Additional information for Patients:

Do not stop or change your diabetes medicines without first talking to your health care professional. When untreated, diabetes can lead to serious problems, including blindness, nerve and kidney damage, and heart disease.

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