Diabetes drug gets FDA warning due to amputation risk

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(HealthDay)—The type 2 diabetes prescription drug canagliflozin (brand

names Invokana, Invokamet, Invokamet XR) appears to increase the risk of leg and foot amputations, the U.S. Food and Drug Administration says.

The FDA is requiring the medications to carry new warnings about the risk. The required warnings on the drug's labeling include the most serious and prominent boxed warning.

The agency's decision is based on data from two large clinical trials showing that leg and foot amputations occurred about twice as often in patients taking canagliflozin as among those taking a placebo.

Amputations of the toe and middle of the foot were the most common, but leg amputations below and above the knee also occurred. Some patients had more than one amputation, some had amputations involving both limbs, according to the FDA.

Type 2 diabetes occurs when the body becomes resistant to insulin. Insulin is a hormone that helps to usher sugar from foods into the body's cells. When this process doesn't work correctly, blood sugar levels rise. Left untreated, high blood sugar levels can cause a number of possible complications, including heart disease, kidney problems and amputations, according to the American Diabetes Association.

Canagliflozin is meant to be 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. These drugs lower blood sugar levels by causing the kidneys to remove sugar from the body through the urine.

It 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.

Patients taking canagliflozin should immediately notify their health care providers if they develop new pain or tenderness, sores or ulcers, or infections in the legs or feet, the FDA said in a news release. Patients should not stop taking their medication without first talking to their health care provider.

Before prescribing canagliflozin to patients, doctors should consider factors that may predispose patients to the need for amputations, including a history of prior amputation, peripheral vascular disease, neuropathy, and diabetic foot ulcers, the FDA said.

In addition, doctors should monitor patients taking canagliflozin for the above signs and symptoms, and discontinue canagliflozin if these complications occur.

In a statement, Janssen Pharmaceuticals, the maker of canagliflozin, said the company had already shared the findings on amputation risk with medical professionals prior to this warning.

"While the incidence was low, the highest incidence of amputations across all treatments was seen in patients with prior amputation," Janssen said.
"At Janssen, patient safety is our highest priority. We are working with FDA to include this information in the prescribing information for canagliflozin."

More information: The American Diabetes Association has more on diabetes complications.

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