



Canagliflozin (Invokana, Invokamet): Drug Safety Communication - Clinical Trial Results Find Increased Risk of Leg and Foot Amputations

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FDA 發布一則藥物安全警訊，一個正在進行的臨床試驗期中分析顯示，降血糖藥物 SGLT2 (sodium-glucose co-transporter 2) 抑制劑 Canagliflozin 可能增加腿部和腳部的截肢風險，主要影響的是腳趾。FDA 目前持續檢視這一個新的安全議題，如果掌握更多的資訊會再做更新。

建議：

醫療人員應該遵循 Canagliflozin 藥物仿單的建議，並監測病患腿部或腳部是否有疼痛、潰瘍或感染的情形。

病患如果在沒有告知醫療人員的情況下自行停止使用藥物，可能會造成血糖控制不穩定，進而導致嚴重的傷害，包括失明，神經損害，腎臟損害，和心臟疾病。病患在使用 Canagliflozin 期間如果發現腿部及腳部有任何新的疼痛、潰瘍或是感染的情形都應該立刻告知醫療人員。

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AUDIENCE: Internal Medicine, Family Practice, Pharmacy, Patient

ISSUE: FDA is alerting the public about interim safety results from an ongoing clinical trial that found an increase in leg and foot amputations, mostly affecting the toes, in patients treated with the diabetes medicine canagliflozin (Invokana, Invokamet). FDA has not determined whether canagliflozin increases the risk of leg and foot amputations. FDA is currently investigating this new safety issue and will update the public when we have more information.

See the FDA Drug Safety Communication for additional details regarding the ongoing Canagliflozin Cardiovascular Assessment Study (CANVAS) clinical trial.

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 lowers blood sugar 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.

RECOMMENDATION: Health care professionals should follow the recommendations in the canagliflozin drug labels. Monitor patients for the signs and symptoms described above and advise patients to seek medical advice if they experience them.

Patients should not stop or change their diabetes medicines without first talking to their health care professional. Doing so can lead to uncontrolled blood sugar levels that can be harmful. Over time, this can cause serious problems, including blindness, nerve and kidney damage, and heart disease. Patients taking canagliflozin should notify their health care professionals right away if they notice any new pain or tenderness, sores or ulcers, or infections in their legs or feet.