

Drug Injury Watch: Invokana / Farxiga / Jardiance: Amputations; Lactic Acidosis; Ketoacidosis

(Posted by Tom Lamb at www.DrugInjuryWatch.com on July 13, 2016)

In July 2016 Boehringer Ingelheim Pharmaceuticals, Inc. received a Supplemental Approval letter from the FDA concerning a label change about fatal cases of ketoacidosis which have been reported concerning Jardiance, Synjardy, and Glyxambi. These relatively new diabetes medicines are part of the Sodium-Glucose Co-Transporter-2 (SGLT2) Inhibitors class of drugs.

In June 2016 the FDA announced it has strengthened the existing warning about the risk of acute kidney injury for Invokana and Invokamet as well as Farxiga and Xigduo XR.

As regards a different type of side effect, we point out this May 2016 document, "FDA Drug Safety Communication: Interim clinical trial results find increased risk of leg and foot amputations, mostly affecting the toes, with the diabetes medicine canagliflozin (Invokana, Invokamet); FDA to investigate".

Since then, we have not heard again from the FDA about the results of this investigation regarding leg, foot, and toe amputations possibly caused by the use of Invokana and Invokamet. But recently the European Medicines Agency (EMA)'s Pharmacovigilance Risk Assessment Committee (PRAC) announced that their investigation about such amputations now includes all the diabetes medicines in the SGLT2 Inhibitors class of drugs, such as Farxiga and Jardiance.

Also in May 2016 a Black-Box Warning about lactic acidosis added to the label for Invokamet, as seen on this FDA Safety Information page, "Invokamet (canagliflozin and metformin HCl) Tablets".

The May 2016 revised Invokana label now includes this drug side effect warning information:

Post-marketing cases of metformin-associated lactic acidosis have resulted in death, hypothermia, hypotension, and resistant bradyarrhythmias. The onset of metformin-associated lactic acidosis is often subtle, accompanied only by nonspecific symptoms such as malaise, myalgias, respiratory distress, somnolence, and abdominal pain....

We will continue to monitor the safety profile for this SGLT2 Inhibitors class of drugs, watching for future label changes with increased side effects warnings, the results of safety investigations by the FDA and the EMA, etc.

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Earlier Invokana / Farxiga / Jardiance articles by attorney Tom Lamb on the [Side Effects Blog](#):

- [FDA: Acute Kidney Injury Due To Invokana, Invokamet, Farxiga, Xigduo](#)
- [Stroke, DVT, Pulmonary Embolism, And Kidney Damage Linked To Invokana](#)
- [When Used By Type 1 Diabetes Patients, Invokana Can Cause Ketoacidosis](#)
- [Invokana Cases Involving Diabetic Ketoacidosis And Kidney Side Effects](#)
- [EMA Says Invokana / Farxiga /Jardiance Linked To Diabetic Ketoacidosis](#)

Attorney [Tom Lamb](#) represents people in personal injury and wrongful death cases involving unsafe prescription drugs or medication errors. The above article was posted originally on his blog, **Drug Injury Watch** – with live links and readers' Comments.
<http://www.DrugInjuryWatch.com>