

Drug Injury Watch: FDA Says Onglyza And Nesina Increase Risks of Heart And Renal Failures

(Posted by Tom Lamb at www.DrugInjuryWatch.com on April 8, 2016)

A recent April 2016 FDA action concerning Onglyza is an update to a February 11, 2014 FDA Drug Safety Communication, and now the FDA is warning about an increased risk of heart failure being linked to Nesina and other diabetes drugs containing alogliptin.

On April 5, 2016 the FDA took regulatory action by mandating that the pharmaceutical companies AstraZeneca and Takeda make label changes for some of their still relatively new diabetes drugs. This move was announced by means of "FDA Drug Safety Communication: FDA adds warnings about heart failure risk to labels of type 2 diabetes medicines containing saxagliptin and alogliptin".

The diabetes drugs covered by this FDA action are:

- AstraZeneca's Onglyza (saxagliptin)
- AstraZeneca's Kombiglyze XR (saxagliptin and metformin extended release)
- Takeda's Nesina (alogliptin)
- Takeda's Kazano (alogliptin and metformin)
- Takeda's Oseni (alogliptin and pioglitazone)

Next we move to the increased risk of renal failure associated with Onlyza, Nesina, and the other diabetes medications containing saxagliptin and alogliptin, as well as some other drugs.

From this March 29, 2016 *Medscape* investigative report, "Possible Drug Risks Buried in Delayed FDA 'Watch Lists'" we learned that the FDA is evaluating the need for regulatory action for the following group of 11 dipeptidyl peptidase IV (DPP-IV) inhibitor drugs due to the serious side effect of renal failure, or kidney failure:

Onglyza (saxagliptin) tablet

Kombiglyze XR (saxagliptin/metformin HCl) extended-release tablet

Nesina (alogliptin) tablet

Kazano (alogliptin/metformin HCl) tablet

Oseni (alogliptin/pioglitazone) tablet

Glyxambi (empagliflozin/linagliptin) tablet

Janumet XR (sitagliptin/metformin HCl) extended release tablet

Janumet (sitagliptin/metformin HCl) tablet

Januvia (sitagliptin) tablet

Jentadueto (linagliptin/metformin HCl) tablet

Tradjenta (linagliptin) tablet

We will continue to watch for reports of heart failure and kidney / renal failure in patients using Onglyza, Nesina, and the other Type-2 diabetes drugs containing saxagliptin and alogliptin.

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Other articles by attorney Tom Lamb on the [Side Effects Blog](#):

- [Diabetes Drugs Like Januvia Linked To Severe Joint Pain Side Effects](#)
- [FDA May Require New Onglyza Drug Label For Warning About Heart Failure](#)
- [Diabetes Drugs Kombiglyze And Onglyza: Heart Failure Side Effect Seems To Be Valid, And FDA Notes There Is A Possible Increased Risk Of All-Cause Mortality](#)
- [Cardiovascular Safety Issues For Onglyza And Kombiglyze Will Be Discussed At April 2015 FDA Advisory Committee Meeting](#)
- [Possible Link Between Heart Failure And Onglyza Diabetes Type 2 Drug Is Being Investigated By FDA, As Announced In February 2014](#)

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>