



FDA Drug Safety Communication: FDA to review heart failure risk with diabetes drug saxagliptin (marketed as Onglyza and Kombiglyze XR)

[02-11-2014] The U.S. Food and Drug Administration (FDA) has requested clinical trial data from the manufacturer of saxagliptin to investigate a possible association between use of the type 2 diabetes drug and heart failure. Our request resulted from a [study](#) published in the *New England Journal of Medicine* (NEJM), which reported an increased rate of hospitalization for heart failure, when the heart does not pump blood well enough, with use of saxagliptin (marketed as Onglyza and Kombiglyze XR) compared to an inactive treatment.¹ The study did not find increased rates of death or other major cardiovascular risks, including heart attack or stroke, in patients who received saxagliptin. The manufacturer is expected to submit the trial data to FDA by early March 2014, after which we will conduct a thorough analysis and report our findings publicly.

At this time, we consider information from the NEJM study to be preliminary. Our analysis of the saxagliptin clinical trial data is part of a broader evaluation of all type 2 diabetes drug therapies and cardiovascular risk.² Patients should not stop taking saxagliptin and should speak with their health care professionals about any questions or concerns. Health care professionals should continue to follow the prescribing recommendations in the drug labels.

Type 2 diabetes is a disease in which there is a high level of sugar, or glucose, in the blood because the body does not make or properly use the hormone insulin. If left untreated, type 2 diabetes can lead to serious problems. Saxagliptin is used along with diet and exercise to lower blood sugar in adults with type 2 diabetes. It works by increasing the amount of insulin produced by the body after meals, when blood sugar is high.

We urge health care professionals and patients to report side effects involving saxagliptin products to the FDA MedWatch program, using the information in the "Contact FDA" box at the bottom of the page.

References:

1. Scirica B et al. Saxagliptin and cardiovascular outcomes in patients with type 2 diabetes mellitus. *New Engl J Med* 2013 Oct 3; 369 (14): 1317-26.
2. Food and Drug Administration. FDA Announces New Recommendations on Evaluating Cardiovascular Risk in Drugs Intended to Treat Type 2 Diabetes. Available at:

<http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/2008/ucm116994.htm>. Accessed January 24, 2014.

Related Information

- [Onglyza prescribing information](#)
- [Onglyza Medication Guide](#)
- [Onglyza safety information](#)
- [Kombiglyze XR prescribing information](#)
- [Kombiglyze XR Medication Guide](#)
- [Kombiglyze XR safety information](#)