Drugs

Early Communication About Safety of Lantus (insulin glargine)

7/1/2009

FDA is aware of four recently-published observational studies that looked at the use of Lantus (insulin glargine) and possible risk for cancer in patients with diabetes. Three of the four studies suggest an increased risk for cancer associated with use of Lantus. See http://www.diabetologia-journal.org/cancer.html.

Based on the currently available data, the FDA recommends that patients *should not* stop taking their insulin therapy without consulting a physician, since uncontrolled blood sugar levels can have both immediate and long-term serious adverse effects. Patients should also contact their healthcare professional if they have concerns about the medicines they are taking.

Similar to human insulin, insulin glargine is used to control blood sugar in people with Type 1 and Type 2 diabetes. Insulin glargine, however, is a modified version of human insulin (an insulin analogue) that allows for the control of blood sugar for extended periods of time (a long-acting insulin). Insulin glargine is approved for once-a-day dosage by subcutaneous injection (injection under the skin).

The four observational studies evaluated large patient databases and all reported some level of association between the use of insulin glargine, and other insulin products, and various types of cancer. The duration of patient follow-up in all four studies was shorter than what is generally considered necessary to evaluate for cancer risk from drug exposure. Further, inconsistencies in findings within and across individual studies raise concerns as to whether an association between the use of insulin glargine and cancer truly exists. Additionally, differences in patient characteristics across the treatment groups may have contributed to a finding of increased cancer risk.

FDA is currently reviewing many sources of safety data for Lantus, including these newly published observational studies, data from all completed controlled clinical trials, and information about ongoing controlled clinical trials, to better understand the risk, if any, for cancer associated with use of Lantus.

Discussions are also ongoing between FDA and the manufacturer of Lantus as to whether any additional studies evaluating the safety and efficacy of this drug will need to be performed.

FDA will communicate the results on its ongoing review to the public, as appropriate, as our review continues.

The FDA encourages both healthcare professionals and patients to report side effects from the use of insulin glargine to the FDA's MedWatch Adverse Event Reporting Program using the information at the bottom of the page.

This early communication is in keeping with FDA's commitment to informing the public about its ongoing safety reviews of drugs. FDA will communicate its findings with the public as soon as its review of insulin glargine is complete.

This information reflects FDA's current analysis of available data concerning this drug. Posting this information does not mean that FDA has concluded there is a causal relationship between the drug product and the emerging safety issue. Nor does it mean that FDA is advising health care professionals to discontinue prescribing this product. FDA is considering, but has not reached a conclusion about whether this information warrants any regulatory action. FDA intends to update this document when additional information or analyses become available.

Related Information

- Diabetologia

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