

April 24, 2008

The extensive body of evidence provided by Sanofi-Aventis in preclinical models and animal toxicology has established that Lantus[®] is a safe product, with similar insulin receptor (IR) affinity as human insulin used as the comparator, and that there is no demonstrated carcinogenicity risk associated with Lantus[®].

The safety of Lantus was extensively reviewed and evaluated during the registration process in the United States, Europe and Japan; as a result of this process, Lantus[®] was granted approval by the competent regulatory authorities in the U.S., Europe and Japan.

Throughout a comprehensive clinical trial program and in clinical use since 2000 with an estimated global exposure of over 15 million patient-years, Lantus has been used safely and effectively by adult and pediatric (6 years and older) patients with type 1 diabetes and adult patients with type 2 diabetes.

Important Safety Information for Lantus[®]

Prescription Lantus[®] is for adults with type 2 diabetes or adults and children (6 years and older) with type 1 diabetes who require long-acting insulin for the control of high blood sugar.

DO NOT DILUTE OR MIX LANTUS[®] WITH ANY OTHER INSULIN OR SOLUTION. It will not work as intended, and you may lose blood sugar control, which could be serious. Do not change your insulin without talking with your doctor. The syringe must not contain any other medication or residue. You should not use Lantus[®] if you are allergic to insulin. Lantus[®] is a long-acting insulin you inject just once a day, at the same time each day. **You must test your blood sugar levels while using an insulin such as Lantus[®].**

The most common side effect of insulin, including Lantus[®], is hypoglycemia, which may be serious. Other possible side effects may include injection site reactions, including changes in fat tissue at the injection site, and allergic reactions, including itching and rash. In rare cases, some allergic reactions may be life threatening. Tell your doctor about other medicines and supplements you are taking because they can change the way insulin works.

For full prescribing information, please see attached file.

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