

FDA approves victoza injection for children 10 years and older

June 18 2019



(HealthDay)—Victoza (liraglutide) injection is now approved to treat

type 2 diabetes in children 10 years and older, the U.S. Food and Drug Administration announced yesterday.

Approved to treat type 2 [diabetes](#) in adults in 2010, Victoza is the first noninsulin drug to be approved to treat type 2 diabetes in children since metformin in 2000. Victoza's labeling states that the injection is not a substitute for insulin and is not indicated for [patients](#) with type 1 diabetes or those with diabetic ketoacidosis. Dosage of Victoza in children should start at 0.6 mg daily for at least one week. The manufacturer's prescribing information indicates that if additional glycemic control is required, the dose should be increased to 1.2 mg daily, and then to 1.8 mg daily after at least one week of treatment with the 1.2-mg daily dose if additional control is still required.

Approval of Victoza in children aged 10 years and older was based on several placebo-controlled trials in adults and one placebo-controlled trial in children. In the trial of 134 children aged 10 years and older, at 26-week follow-up, HbA1c levels reduced to less than 7 percent for approximately 64 percent of children treated with Victoza compared with 37 percent of children treated with placebo. Researchers found similar results when patients were also taking insulin simultaneously.

Although Victoza has been indicated to reduce the risk for major adverse cardiovascular events in adults with type 2 diabetes, the FDA notes that the drug's effect on major adverse cardiovascular events in children has not been studied, and it is therefore not indicated to reduce the risk for these events in [children](#). Children aged 10 years and older who are taking Victoza have an increased risk for hypoglycemia even without additional therapies for diabetes. Due to an increased risk for thyroid C-cell tumors, Victoza is contraindicated in patients who have had medullary thyroid carcinoma, those with [family members](#) who have had medullary thyroid carcinoma, and patients with multiple endocrine neoplasia syndrome type 2.

Approval of Victoza was granted to Novo Nordisk.

More information: [More Information](#)

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Citation: FDA approves victoza injection for children 10 years and older (2019, June 18)
retrieved 21 March 2023 from <https://medicalxpress.com/news/2019-06-fda-victoza-children-years-older.html>

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