THE OFFICIAL NEWSMAGAZINE OF THE AMERICAN ACADEMY OF PEDIATRICS
AAP News

News Articles, FDA Update, Diabetes Mellitus, Pharmacology

FDA approves 2 products to treat diabetes in pediatric patients

by from the Food and Drug Administration's Office of Pediatric Therapeutics, Division of Pediatric and Maternal Health, and Division of Metabolism and Endocrinology Products

The Food and Drug Administration (FDA) recently approved the first non-insulin drug since metformin to treat type 2 diabetes mellitus (T2DM) in pediatric patients and the first glucagon therapy for the emergency treatment of severe hypoglycemia that can be administered without an injection.

Victoza (liraglutide) is a glucagon-like peptide-1 receptor agonist used as an adjunct to diet and exercise to improve glycemic control in pediatric patients 10 years and older with T2DM. This marks the first pediatric T2DM drug approval since metformin in 2000 and human insulin in 1982.

Victoza, a subcutaneous injection given once daily, was approved for adults in 2010. The prevalence of T2DM among children is increasing, concurrent with the obesity epidemic. Additional antidiabetic therapy added to metformin to achieve adequate glycemic control often is needed in adolescents.

The approval of Victoza in pediatric patients was supported by a 26-week placebo-controlled clinical trial in patients on metformin, with a 26-week open-label extension in 134 patients 10-17 years of age with T2DM, a pediatric pharmacokinetic study and studies in adults with T2DM. Use of Victoza was associated with greater reduction of hemoglobin A1C compared to placebo. The risk of hypoglycemia was higher in pediatric patients who took Victoza compared to adults regardless of concomitant antidiabetic therapies, including insulin. Victoza is not recommended for treatment of type 1 diabetes mellitus or diabetic ketoacidosis.

The FDA also approved Baqsimi (glucagon) nasal powder, the first glucagon therapy approved for the emergency treatment of severe hypoglycemia that can be administered without an injection. Severe hypoglycemia can cause confusion or unconsciousness from the low blood sugar level, requiring help from another person.

Use in pediatric patients 4 years and older is based on a comparative study between Baqsimi and intramuscular glucagon in 58 patients. In both treatment groups, glucose increased within 20 minutes after insulin-induced reduction of blood glucose to low normal levels or reduction of blood glucose to less than 80 mg/dL.

Typically, severe hypoglycemia occurs in people with diabetes who are using insulin treatment. However, certain non-insulin antidiabetic agents may cause hypoglycemia, particularly when used with insulin or sulfonylureas.

Baqsimi is a powder administered into the nose. It will come in a single-use dispenser that can be given to patients with type 1 or type 2 diabetes experiencing a severe hypoglycemic episode.

Resources

- Victoza prescribing information
- Baqsimi prescribing information
- Additional FDA Update columns

Copyright © 2019 American Academy of Pediatrics