FDA approves first noninjection glucagon therapy

July 25 2019

(HealthDay)—The U.S. Food and Drug Administration has approved the

first noninjection glucagon therapy for emergency treatment of severe hypoglycemia, the agency announced late yesterday.

Baqsimi nasal powder, which was approved for patients with diabetes who are 4 years and older, is available in a single-use dispenser containing a recommended dose of 3 mg.

Approval was based on two studies of adult patients and one study in children—all comparing a single dose of Baqsimi to a single dose of glucagon injection. In all three studies, researchers concluded that Baqsimi was noninferior to intramuscular injection in reversing insulin-induced hypoglycemia. In the first study of 70 adult patients, 100 percent of patients had treatment success at a mean time of 11.6 and 9.9 minutes in the Baqsimi and injection groups, respectively. In the second study of 83 patients, 98.8 percent of patients in the Baqsimi group and 100 percent of patients in the injection group achieved treatment success at a mean time of 15.9 and 12.1 minutes, respectively. In the study of 48 type 1 diabetes patients aged 4 years and older, patients in both groups had an increase in glucose ≥20 mg/dL from glucose nadir within 20 minutes of administration.

The most commonly reported adverse reactions included nausea, vomiting, headache, upper respiratory tract irritation, watery eyes, eye redness, and itchiness. Baqsimi is contraindicated in patients with pheochromocytoma or insulinoma and those with known hypersensitivity to glucagon or Baqsimi's inactive ingredients. The powder's prescription information includes a warning to use it with caution in patients who have been fasting for long periods, have adrenal insufficiency, or have chronic hypoglycemia.

Approval was granted to Eli Lilly and Company. According to a company press release, Baqsimi is expected to be available in retail pharmacies within a month.

More information: More Information

Health News