

FDA Approves Once-Weekly Basal Insulin Efsitora for Type 2 Diabetes

The FDA has approved efsitora (Onswik), a once-weekly basal insulin, for adults with type 2 diabetes as an adjunct to diet and exercise. The therapy provides sustained basal insulin coverage over seven days. It is not approved for children or for type 1 diabetes, where it carries a higher risk of severe hypoglycemia.

Onswik is designed to deliver steady basal insulin levels over a full seven days.

"For over a century, Lilly has been developing insulins that transformed diabetes care for millions of people worldwide, but delays in initiating treatment and the burden of daily injections can have a real impact on patients' day-to-day experience managing type 2 diabetes," said Kenneth Custer, Ph.D., executive vice president and president, Lilly Cardiometabolic Health. "Onswik offers a new once-weekly basal insulin option for patients and reflects our continued commitment to deliver innovative treatment options that expand choice and provide greater flexibility in how people manage type 2 diabetes."

This is the fourth global approval for Onswik for adults with type 2 diabetes, following regulatory actions from the European Medicines Agency (EMA), Mexico's Federal Commission for the Protection against Sanitary Risks (COFEPRIS) and Japan's Pharmaceuticals and Medical Devices Agency (PMDA).

The FDA approval is based on data from the QWINT Phase 3 clinical trials, which evaluated the safety and efficacy of once-weekly Onswik in over 3,400 adults with type 2 diabetes. In each QWINT trial, once-weekly Onswik met the primary endpoint of non-inferior A1C reduction from baseline that was comparable to insulin glargine U-100 (glargine) or insulin degludec U-100 (degludec).

In these clinical trials, Onswik demonstrated an overall safety profile similar to the daily basal insulins studied.³⁻⁶ Onswik should not be used by people who have type 1 diabetes due to increased risk of severe hypoglycemia (low blood sugar). Common side effects of Onswik include low blood sugar, allergic reactions, reactions at the injection site, skin thickening or pits at the injection site (lipodystrophy), itching, rash, swelling of hands and feet, and weight gain.

Around one in eight Americans live with diabetes, and most of them have type 2 diabetes.⁷ Globally by 2030, over 510 million people are expected to live with the disease and 38 million of these are expected to use insulin.⁸ Insulin remains an important treatment option for many people with type 2 diabetes who do not achieve glycemic goals with other therapies.

The Onswik™ KwikPen® will be available in the U.S. in the coming months in two concentrations: 500 units/mL (contains 1,500 units total) and 1,000 units/mL (contains 3,000 units total).

News Source:

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