

FDA OKs First Fast-Acting Insulin Biosimilar for Diabetes

The FDA has approved a new fast-acting insulin biosimilar to help manage blood sugar in people with diabetes, including children and adults.

The product, called Merilog, is the first fast-acting insulin biosimilar to get a federal nod. Biosimilars are near-identical versions of FDA-approved biologic drugs, offering the same safety and effectiveness.

Diabetes is a condition where blood sugar (or glucose) levels get too high because the body can't make or use insulin properly. Insulin, made by the pancreas, helps move sugar into cells for energy. Without enough insulin, blood sugar builds up, leading to health problems. In the United States, over 38 million people have diabetes, and about 8.4 million rely on insulin to manage their blood sugar. With more people needing daily insulin, biosimilar options can make this lifesaving treatment more accessible.

Merilog, made by Sanofi-Aventis, is a rapid-acting insulin biosimilar (similar to Novo Nordisk's Novolog) that helps control blood sugar spikes when taken five to 10 minutes before a meal. Merilog is injected under the skin — typically in the stomach, thighs, buttocks, or upper arms. The dose should be tailored to a patient's needs, the FDA said.

Common side effects of Merilog include skin reactions or changes in skin texture where the needle went in the skin, itching, rash, weight gain, and swelling in the hands and feet. It can also cause serious side effects like low blood sugar and potassium levels and severe allergies.

News Source:

<https://www.webmd.com/diabetes/news/20250220/fda-oks-first-fast-acting-insulin-biosimilar-diabetes>