COMMUNICATION

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PLEASE REVIEW

Drug Information

PharmPix Clinical Department

PharmPix is committed to the health and wellness of our members.

The clinical team wants to communicate the latest up-to-date drug information requested.

Drug Information:

Remember that medical literature is dynamic and is continuously changing as new scientific knowledge is developed. We exhort the frequent revision of treatment guidelines to assure that your recommendations are consistent with the most updated information.

It is our priority to offer high-quality services and support practices for health promotion and diseases prevention. If you have any questions or wish to have more information regarding this document, you can call us directly or view PharmPix communications online.

QUESTIONS

Call us at 787-522-5252-ext 219.

Access our recent communications at our providers' portal: https://www.pharmpix.com/providers/.

FDA Approves First Novolog (Insulin Aspart) Biosimilar

The U.S. Food and Drug Administration (FDA) announced on February 14, 2025, the approval of Merilog (insulin-aspart-szjj) as a biosimilar to Novolog (insulin aspart) for the improvement of glycemic control in adults and pediatric patients with diabetes mellitus.

Merilog (insulin-aspart-szjj)

Merilog is a fast-acting human insulin analog and represents the first rapid-acting insulin biosimilar to receive FDA approval. It aids in reducing blood sugar spikes during meals, contributing to better blood sugar management for individuals with diabetes. The approval covers a 3-milliliter prefilled pen for single-patient use and a 10-milliliter vial for multiple doses.

Merilog is the third insulin biosimilar to gain approval after two insulin glargine biosimilars: Semglee (insulin glargine-yfgn) and Rezvoglar (insulin glargine-agar).

Over 38 million individuals in the United States have been diagnosed with diabetes. Around 8.4 million Americans depend on insulin therapy, including rapid-acting and/or long-acting insulin, to control their diabetes. Insulin, a hormone produced by the pancreas, assists in moving glucose into the cells for energy use.

Similar to Novolog, Merilog should be injected 5 to 10 minutes before eating. It is given through a subcutaneous (under-the-skin) injection.

Merilog can lead to serious side effects, such as hypoglycemia (low blood sugar), severe allergic reactions, and hypokalemia (low potassium levels). Common side effects may include reactions at the injection site, itching, rash, lipodystrophy (skin thickening or indentations at the injection site), weight gain, and swelling in the hands and feet.

Additional information can be found at: https://www.fda.gov/news-events/press-announcements/fda-approves-first-rapid-acting-insulin-biosimilar-product-treatment-diabetes

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REFERENCES:
1. U.S. Food and Drug Administration. (2025, February 14*). FDA approves first rapid-acting insulin biosimilar product for treatment of diabetes*. U.S. Food and Drug Administration. https://www.fda.gov/news-events/press-announcements/fda-approves-first-rapid-acting-insulin-biosimilar-product-treatment-diabetes
2. Center for Biosimilars. (2025, February 17). *FDA approves first insulin aspart biosimilar*. Center for Biosimilars. https://www.centerforbiosimilars.com/view/fda-approves-first-insulin-aspart-biosimilar

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