

Insulin Glargine Injection Pens

July 5, 2022 – Mylan Pharmaceuticals Inc., a Viatris company, is voluntarily recalling one batch of Insulin Glargine (Insulin glargine-yfgn) Injection, 100 units/mL (U-100), 3 mL prefilled pens which are packaged in cartons of five pens to the consumer level. This product is not the branded Semglee® pen but the unbranded Insulin Glargine-yfgn pens. This batch is being recalled due to the potential for the label to be missing on some pens.

Risk Statement: For patients receiving treatment with more than one type of insulin (e.g., both short and long-acting insulin), a missing label on Insulin Glargine pens could lead to a mix-up of products/strengths, which may result in less optimal glycemic control (either high or low blood sugar) which could result in serious complications. To date, no adverse events related to this recall have been received for this product.

This recall pertains **only** to the unbranded interchangeable biosimilar Insulin Glargine-yfgn pens and does not impact the branded interchangeable biosimilar Semglee® (insulin glargine-yfgn) injection pens.

This product is a long-acting human insulin analog indicated to improve glycemic control in adults and pediatric patients with type 1 diabetes mellitus and in adults with type 2 diabetes mellitus. The product is packaged in a 3 mL prefilled pen which is then packaged in cartons of five pens. The product information, batch number and expiry date information are present on the carton.

This batch was manufactured by Biocon Sdn. Bhd. and was distributed by Mylan Specialty L.P. in the US between April 4, 2022 and May 5, 2022. The recalled batch information is as follows:

NDC #	Name and Strength	Size	Batch #	Expiry
49502-394-75	Insulin Glargine (Insulin glargine-yfgn) Injection, 100 units/mL (U-100)	3 mL Prefilled Pen	BF21002895	Aug 2023

- **Consumers:** If you have an unlabeled pen, please contact Sedgwick at 1-877-643-8438 for the documentation packet to return the product.

Consumers with questions regarding this recall can contact Viatris Customer Relations by phone at 1-800-796-9526 or by email at customer.service@viatris.com, Monday through Friday from 8 a.m. – 5 p.m. EST. Consumers should contact their physician or healthcare provider if they have experienced any problems that may be related to taking or using this drug product.