RXADVANCE
136 Turnpike Road
Southborough, MA 01772

Levemir®, Tresiba®, Fiasp®, Novolog® and Xultophy® Recall Alert

Date of Notice: 05/10/2021

Brief Description of Recall Alert

Novo Nordisk is voluntarily recalling 1,468 product samples listed in the table below of Levemir®, Tresiba®, Fiasp®, Novolog®, and Xultophy®. These products are being recalled because they were stored at temperatures below storage requirements. This recall only impacts product samples and does not impact product that have been distributed to retail and mail-order pharmacies.

If product samples are exposed to temperatures below 32°F, it could cause a lack of efficacy and damage to the cartridge and pen-injectors. If product from an improperly stored vial, cartridge, or pen-injector is used, there is a risk that you might not receive the right amount of medicine as intended which may lead to hyperglycemia (high blood sugar) or hypoglycemia (low blood sugar) resulting in adverse health consequences ranging from limited to life-threatening.

These products are used to lower blood glucose levels in people with diabetes and are packaged in cartons with either a vial, pen-injector (FlexPen® or FlexTouch®), or a cartridge (PenFill®). A list of the affected lots can be found in the chart below:

Affected Products

Drug Name & Strength	NDC	Lot	Expiration Date
Fiasp® FlexTouch®	00169-3204-90 (Pen) 00169-3204-97 (Kit)	KP51207 KP52618	06/30/2022 10/31/2022
Fiasp® PenFill®	00169-3205-91	KS6BF84 KS6BX63	06/30/2022 10/31/2022
Fiasp® Vial	00169-3201-90 00169-6438-90 (Pen)	KS6AK76 KS6BR92	05/31/2022 09/30/2022
NovoLog® FlexPen®	00169-5339-98 (Kit)	KS6BS11	11/30/2021
NovoLog® Vial	00169-7501-90	JZFC826 KZFM305 JP52771 JP53136 KP50575 KP50976 KP51813	06/30/2021 08/31/2022 09/30/2021 06/30/2021 01/31/2021 01/31/2022 04/30/2022
Tresiba® U100	00169-2660-90 (Pen)	KP52035	04/30/2022
Tresiba® FlexTouch®	00169-2660-97 (Kit)	KP52117 KP52440 KP52461	04/30/2022 06/30/2022 04/30/2022

		KP52616 JP52361 KP52829 JP54181	06/30/2022 08/1/2021 07/31/2022 09/30/2021
Tresiba® U200	00169-2550-90 (Pen)	KP51059	11/30/2021
Tresiba® FlexTouch®	00169-2550-97 (Kit)	KP51865 KP54179 JP52179	11/30/2021 11/30/2022 08/16/2021
Tresiba® Vial	00169-2662-90	JZFE233	11/30/2021
Xultophy® Pen	00169-2911-97 (Kit)	JP54291	06/20/2021

Prescriber Information

The product can be identified by looking for the batch number or lot number located on the product carton and matching it to the list above. Novo Nordisk has notified all doctor offices that received affected samples and requested all impacted samples be returned. Members who received an affected sample through the doctor's office should have received a letter from their doctor. If product samples match a batch number above or there are any questions about the recall, please contact the Novo Nordisk recall processor Inmar at 1-888-686-5002, Monday through Friday, 9:00 AM to 5:00 PM EDT. Novo Nordisk has not received any reports of serious adverse events or injuries related to this recall.

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail, or by fax.

- Complete and submit the report Online
- Regular Mail or Fax: Download form or call 1- 800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178

Member Information

Please report any complaints and adverse events to Novo Nordisk's Customer Care Center which can be reached at 1-800-727-6500, Monday through Friday, 8:30 AM to 6:00 PM EDT.

RxAdvance Response

RxAdvance recommends that you speak to your doctor or healthcare provider about concerns regarding this recall.