COMPANY ANNOUNCEMENT

Novo Nordisk Issues Voluntary Nationwide Recall of Levemir®, Tresiba®, Fiasp®, Novolog® and Xultophy® Product Samples Due to Improper Storage Temperature Conditions

Summary

Company Announcement Date:

May 07, 2021

FDA Publish Date:

May 10, 2021

Product Type:

Drugs

Reason for Announcement:

Due to improper storage temperature conditions

Company Name:

Novo Nordisk

Brand Name:

Levemir, Tresiba, Fiasp, Novolog and Xultophy

Product Description:

Product Samples

Company Announcement

Novo Nordisk is voluntarily recalling 1,468 product samples listed in the table below of Levemir®, Tresiba®, Fiasp®, Novolog® and Xultophy®, to the consumer level. 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 has been broadly distributed to pharmacies or mail-order services.

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 or hypoglycemia resulting in adverse health consequences ranging from limited to life-threatening. Novo Nordisk has not received any reports of serious adverse events or injuries related to this recall.

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:

Product Name	NDC #	Batch #	# of Affected Samples	Expiration Date
Fiasp® FlexTouch®	0169-3204-90 (Pen)	KP51207	24	06/30/2022
	0169-3204-97 (Kit)	KP52618	153	10/31/2022
Fiasp® PenFill®	0169-3205-91	KS6BF84	7	06/30/2022
		KS6BX63	90	10/31/2022
Fiasp® Vial	0169-3201-90	KS6AK76	10	05/31/2022
		KS6BR92	20	09/30/2022
	0169-6438-90 (Pen)		24	
Levemir® FlexTouch®	0169-6438-98 (Kit)	KP51933		07/31/2022
	0169-6339-90 (Pen)		44	
NovoLog® FlexPen®	0169-5339-98 (Kit)	KS6BS11		11/30/2021
NovoLog® Vial	0169-7501-90	JZFC826	17	06/30/2021
		KZFM305	26	08/31/2022
		JP52771	13	09/30/2021
		JP53136	4	06/30/2021
		KP50575	30	01/31/2021
		KP50976	27	01/31/2022
		KP51813	99	04/30/2022
Tresiba® U100	0169-2660-90 (Pen)	KP52035	12	04/30/2022
FlexTouch®	0169-2660-97 (Kit)	KP52117	36	04/30/2022
		KP52440	207	06/30/2022

		KP52461	60	04/30/2022
		KP52616	81	06/30/2022
		JP52361	7	08/1/2021
		KP52829	170	07/31/2022
		JP54181	12	09/30/2021
Tresiba® U200	0169-2550-90 (Pen)	KP51059	8	11/30/2021
FlexTouch®	0169-2550-97 (Kit)	KP51865	182	11/30/2021
		KP54179	68	11/30/2022
		JP52179	20	08/16/2021
Tresiba® Vial	0169-2662-90	JZFE233	14	11/30/2021
	0169-2911-90 (Pen)			
Xultophy® Pen	0169-2911-97 (Kit)	JP54291	3	06/20/2021

The product can be identified by looking for the batch number or lot number located on the product or carton and matching it to the list above. Novo Nordisk has notified all physician offices that received affected samples and requested all impacted samples be returned. Customers who received an affected sample through the physician's office should have received a letter from their physician. 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.

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.

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 (/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program/reporting-serious-problems-fda)
- Regular Mail or Fax: Download form (/safety/medical-product-safety-information/medwatch-forms-fda-safety-reporting) 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

This recall is being conducted with the knowledge of the U.S. Food and Drug Administration.

About Novo Nordisk

Novo Nordisk is a global healthcare company that's been making innovative medicines to help people with diabetes lead longer, healthier lives for 95 years. This heritage has given us experience and capabilities that also enable us to help people defeat other serious diseases including obesity, hemophilia and growth disorders. We remain steadfast in our conviction that the formula for lasting success is to stay focused, think long-term and do business in a financially, socially and environmentally responsible way. With U.S. headquarters in New Jersey and production and research facilities in six states, Novo Nordisk employs nearly 6,000 people throughout the country. For more information, visit novonordisk.us (http://www.novonordisk-us.com/) (http://www.fda.gov/about-fda/website-policies/website-disclaimer), Facebook (https://www.facebook.com/NovoNordiskUS/) (http://www.fda.gov/about-fda/website-policies/website-disclaimer), Instagram (https://www.instagram.com/novonordiskus/) (http://www.fda.gov/about-fda/website-policies/website-disclaimer) and Twitter (https://twitter.com/novonordiskus) (http://www.fda.gov/about-fda/website-policies/website-disclaimer).

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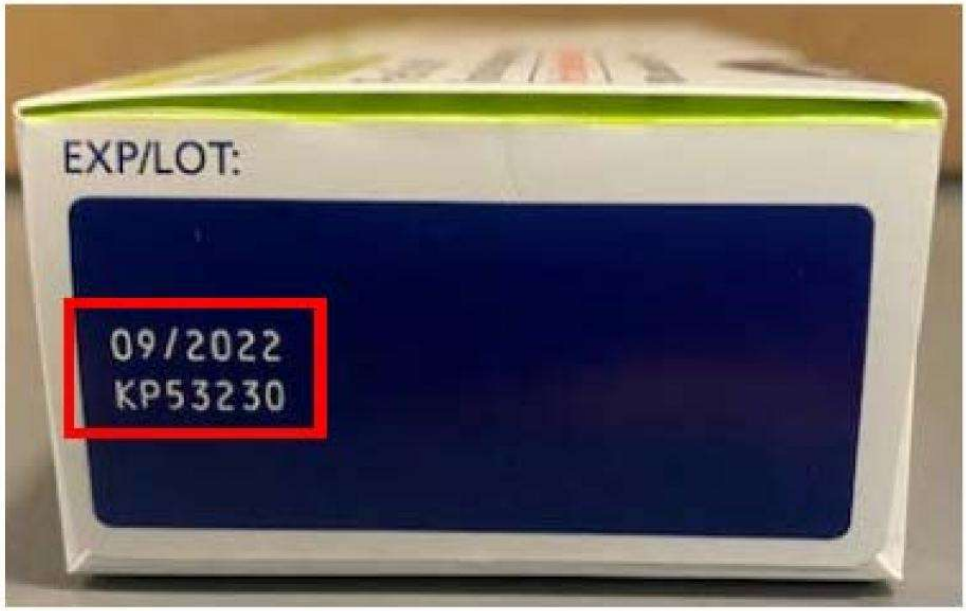
Consumers:

Novo Nordisk recall processor Inmar

1-888-686-5002

Product Photos



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B

More Recalls, Market Withdrawals, & Safety Alerts (/safety/recalls-market-withdrawals-safety-alerts)