Clifton Health Department
Food Recall Notification

Food/Drug/Pet Recall: Novo Nordisk

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
. 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
This recall is being conducted with the knowledge of the U.S. Food and Drug Administration.
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No action is required of local health departments at this time for any of these recalls and alerts. If any requests for assistance are received from FDA, the Public Health and Food Protection Program will contact you. For additional information regarding warnings and recalls, please click on the weblink below.
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For all recalls - http://www.recalls.gov/recent.html