

## Company Announcement

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# Novo Nordisk Inc. issues voluntary nationwide recall of six batches of GlucaGen® HypoKit® (glucagon [rDNA origin] for injection) due to detached needles on the syringe in the kit

## For Immediate Release

September 8, 2016

## Contact

### Consumers

Customer Service  
☎ 1-888-840-1137

### Media

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## Announcement

[View Product Photos](#)

Plainsboro, NJ - Novo Nordisk Inc. is recalling six batches of the GlucaGen® HypoKit® in the U.S. due to two customer complaints from the UK and Portugal involving detached needles on the syringe with Sterile Water for Injection (SWFI). GlucaGen® HypoKit® is indicated for the treatment of severe hypoglycemia (low blood sugar) in

patients with diabetes who are treated with insulin. A syringe with a detached needle cannot be used as prescribed.

Untreated hypoglycemia can eventually lead to unconsciousness and seizures, which can prove fatal. If the blood glucose levels are not quickly restored, continuing hypoglycemia can lead to a decline in brain glucose levels which manifests through a variety of symptoms including cognitive dysfunction, sweating, tremors, convulsion and eventually coma or death.

Novo Nordisk conducted an investigation which showed that a small number (0.006%) of needles could be detached from the syringe in certain batches of GlucaGen® HypoKit®. To protect patient safety, Novo Nordisk is recalling affected batches from wholesalers, pharmacies and patients in the U.S. It is estimated that out of the 71,215 pens being recalled, four pens could be defective.

This recall includes GlucaGen® HypoKit® batch numbers:

- Batch: FS6X270, Expiry: 09/30/2017
- Batch: FS6X296, Expiry: 09/30/2017
- Batch: FS6X538, Expiry: 09/30/2017
- Batch: FS6X597, Expiry: 09/30/2017
- Batch: FS6X797, Expiry: 09/30/2017
- Batch: FS6X875, Expiry: 09/30/2017

The affected products were distributed starting February 15, 2016.

Novo Nordisk is working as quickly as possible and in collaboration with the U.S. Food and Drug Administration (FDA) to recall affected products from the marketplace, including those in the possession of patients. To date, Novo Nordisk is not aware of any known adverse events resulting from the use of the recalled batches.

Patients or caregivers should check the batch number to see if their GlucaGen® HypoKit® is affected. The batch number is printed on the GlucaGen® HypoKit® as indicated below in the red box (Figure 1).

Figure 1. A) GlucaGen® HypoKit® where the batch number is found in the red box, B) close up of the batch number.

If you have a GlucaGen® HypoKit® with one of the above-mentioned batch numbers, call 1-888-840-1137 from Monday to Friday, between 8:30am - 6:00pm Eastern Time, to find out how to return the product. Novo Nordisk will provide reimbursement for out-of-pocket costs incurred for the purchase for your affected GlucaGen® HypoKit® with proof of purchase. If you received a GlucaGen® HypoKit® through the Novo Nordisk Patient Assistance Program, you will receive a replacement device.

If you are in possession of a GlucaGen® HypoKit® with a batch number NOT mentioned above, the product is not subject to the recall and may be used as prescribed.

Novo Nordisk Inc. is notifying its distributors and customers by letter and phone and is arranging for return of all recalled products.

Adverse reactions or quality problems experienced with the use of this product may be reported to Novo Nordisk by calling 1-800-727-6500. Patients can also call the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

- Complete and submit the report Online: [www.fda.gov/medwatch/report.htm](http://www.fda.gov/medwatch/report.htm)  
(<http://www.fda.gov/medwatch/report.htm>)
- Regular Mail or Fax: Download form [www.fda.gov/MedWatch/getforms.htm](http://www.fda.gov/MedWatch/getforms.htm)  
(<http://www.fda.gov/MedWatch/getforms.htm>) 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.

Novo Nordisk is committed to patient safety and delivering high-quality medicines, and is working to take corrective actions and avoid re-occurrence.

## Indications and Usage

What is GlucaGen® (glucagon [rDNA origin] for injection) HypoKit®?

GlucaGen® HypoKit® is a prescription medicine used to treat very low blood sugar (severe hypoglycemia) in people with diabetes who use insulin.

## Important Safety Information

Who should not use GlucaGen® HypoKit®?

Do not use GlucaGen® HypoKit® if:

- you are allergic to glucagon or lactose or any of the ingredients in GlucaGen® HypoKit®
- you have a tumor in the gland on top of your kidneys (adrenal gland) called a pheochromocytoma
- you have a tumor in your pancreas called an insulinoma

What should I tell my doctor before using GlucaGen® HypoKit®?

Before using GlucaGen® HypoKit®, tell your doctor about all of your medical conditions, including if you:

- have kidney problems
- have pancreas problems. Tumors in your pancreas called glucagonomas
- have not had food or water for a long time (prolonged fasting or starvation)
- have low blood sugar that does not go away (chronic hypoglycemia)
- have heart problems
- are pregnant, plan to become pregnant, are breastfeeding, or plan to breastfeed. It is not known if GlucaGen® HypoKit® passes into your breast milk

Tell your doctor about all the medicines you take, including prescription and over-the-counter medicines, vitamins and herbal supplements. GlucaGen® HypoKit® may affect the way other medicines work, and other medicines may affect how GlucaGen® HypoKit® works.

How should I use GlucaGen® HypoKit®?

- Read the detailed Instructions for Use that come with GlucaGen® HypoKit®.
- Use GlucaGen® HypoKit® exactly as your doctor tells you to.
- Make sure that you and your family know how to use GlucaGen® HypoKit® the right way before you need it.
- Act quickly. Having low blood sugar for a period of time may be harmful.

Call for emergency medical help right after you use GlucaGen® HypoKit®.

- Eat sugar or a sugar-sweetened product such as a regular soft drink or fruit juice as soon as you are able to swallow.
- Tell your doctor each time you use GlucaGen® HypoKit®. Your doctor may need to change the dose of your diabetes medicines.

What should I avoid while using GlucaGen® HypoKit®? While using GlucaGen® HypoKit® do not:

- drive or operate machinery until you have eaten sugar or a sugar-sweetened product such as a regular soft drink or fruit juice.

What are the possible side effects of GlucaGen® HypoKit®? GlucaGen® HypoKit® may cause serious side effects, including:

- High blood pressure. High blood pressure is common after taking GlucaGen® HypoKit® and can be severe.
- Low blood sugar. GlucaGen® HypoKit® can cause low blood sugar in patients with tumors in their pancreas called insulinomas and glucagonomas by making too much insulin in their bodies.
- Allergic reactions. Symptoms of a serious allergic reaction to GlucaGen® HypoKit® may include rash, difficulty breathing, or low blood pressure (hypotension).

The most common side effects of GlucaGen® HypoKit® include nausea, vomiting, temporary fast heartbeat or pounding in your chest (tachycardia).

Tell your doctor if you have any side effect that bothers you or that does not go away. **[Please click here for the GlucaGen® HypoKit® Prescribing Information and \(http://www.novo-pi.com/glucagenhypokit.pdf\)](http://www.novo-pi.com/glucagenhypokit.pdf)**  
**[GlucaGen® HypoKit® Patient Information. \(http://www.novo-pi.com/glucagenhypokit.pdf\)](http://www.novo-pi.com/glucagenhypokit.pdf)**

About Novo Nordisk

Novo Nordisk is a global healthcare company with more than 90 years of innovation and leadership in diabetes care. This heritage has given us experience and capabilities that also enable us to help people defeat other serious chronic conditions: hemophilia, growth disorders and obesity. With U.S. headquarters in Plainsboro, N.J., Novo Nordisk Inc. has more than 5,000 employees in the United States. For more information, visit [novonordisk.us](http://novonordisk.us) or follow us on Twitter: [@novonordiskus](https://twitter.com/novonordiskus).

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