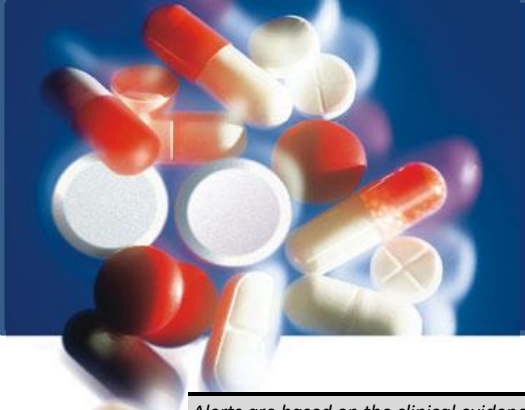

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Alerts are based on the clinical evidence available at the time of publication. Recommendations are intended to assist practitioners in providing consistent, safe, high quality, and cost effective drug therapy. They are not intended to interfere with clinical judgment. When using dated material, the clinician should consider new clinical information, as available and applicable.

PBM-2016-10 **SEPTEMBER 14, 2016**

ITEM: **GlucaGen® HypoKit® (glucagon [rDNA origin] for injection) recall due to detached needles on the syringe in the kit**

SPECIFIC INCIDENT(S): Novo Nordisk Inc. is recalling six batches of the GlucaGen® HypoKit® due to detached needles on the syringe with Sterile Water for Injection (SWFI).

GENERAL INFORMATION:

- GlucaGen® HypoKit® is indicated for the treatment of severe hypoglycemia in patients with diabetes treated with insulin.
- Untreated hypoglycemia can result in cognitive dysfunction, sweating, tremors, convulsion, coma, and/or death.
- Affected products were distributed starting February 15, 2016, and include the following batch numbers (associated with NDC # = 00169-7065-15):
  - 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
- No known adverse events have resulted from the use of the recalled batches.
- This alert is an extension of the product sequestration actions in **Product Recall Office Log # 11110** (available at: http://vaww.recalls.ncps.med.va.gov/WebRecalls/Recalls.html).
- Providers should continue to report any adverse reactions with the use of GlucaGen® HypoKit® by entering the information into CPRS' Allergies/ Adverse Reactions field and/or via local reporting mechanisms. Adverse events should also be reported, as appropriate, to the VA ADERS program and FDA MedWatch (1-800-FDA-1088, fax 1-800- FDA-0178, online at https://www.accessdata.fda.gov/scripts/medwatch/medwatch- online.htm, or by mail).

ACTIONS:

PROVIDER NOTIFICATION:

- **Facility Director** (or physician designee): Forward this document to the Facility Chief of Staff (COS).
- **Facility COS** (and Chief Nurse Executives): Forward this document to all appropriate

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providers who prescribe this agent (e.g., **primary care providers, endocrinologists, and pharmacy staff, including contract providers**, etc.). In addition, forward to the Associate Chief of Staff (ACOS) for Research and Development (R&D). Forward to other VA employees as deemed appropriate.

- **ACOS for R&D:** Forward this document to Principal Investigators (PIs) who have authority to practice at the facility and to your respective Institutional Review Board (IRB).

PATIENT NOTIFICATION:

- **Chief of Pharmacy:** Within 10 business days of issue (due 9/28/2016):
  - Determine whether the affected product(s) was dispensed to any patient(s) for home administration. CMOP data will be provided by a CMOP representative to Pharmacy Chiefs.
  - If an affected batch was dispensed to any patient(s) for home administration, then:
    - Identify the patient(s).
    - Contact the patient(s) who may have received the affected product(s) for home administration by letter (or other means).
      - A sample letter can be found at: https://vaww.cmopnational.va.gov/cmop/PBM/Other%20Documents%20and%20Resources/ASA%20Recall%20Patient%20Letter%20Template. doc .
      - This template can be altered according to site-specific needs.
    - Provide patient(s) in possession of the recalled product with instructions on the following:
      - How to inspect affected product for needles that are detached from the syringes.
      - How to return the product being recalled to the pharmacy.
      - How to obtain a new supply of product.
      - Patients should not continue to use the product until they obtain replacement product.
      - When the correct product is received, patients should begin using the new product and return the recalled supply as instructed.
  - Communicate to PBM/VAMedSAFE that all patient notification actions have been completed via the VHA Alerts and Recalls Website: http://vaww.recalls.ncps.med.va.gov/WebRecalls/Recalls.html.

SOURCE: FDA

REFERENCE(S): 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.

http://www.fda.gov/Safety/Recalls/ucm519872.htm?source=govdelivery&utm_medium=email&utm_source=govdelivery . Accessed September 12, 2016.

ATTACHMENT(S): None.

CONTACTS: Pharmacy Benefits Management Services (PBM) at (708)786-7862.