Novo Nordisk – Recall of NovoPen Echo® insulin cartridge holder

- On July 5, 2017, the FDA announced a patient-level recall of some batches of Novo Nordisk's NovoPen Echo insulin cartridge holders because they may crack or break if exposed to certain chemicals, like certain cleaning agents.

- The recalled batches were distributed between 8/1/2016 – 6/22/2017.

Product Description	NDC #	Batch #
NovoPen Echo	00169-1854-59	EVG1221, EVG1226, FVG7149, FVG7458, FVG8134, FVG8135

- NovoPen Echo is a device used for insulin treatment by people with diabetes.

- Using the NovoPen Echo with a cracked/broken cartridge holder may result in the device delivering a reduced dose of insulin which could potentially lead to hyperglycemia.

    — The warning signs of hyperglycemia typically appear gradually and might include flushed, dry skin; feeling sleepy or tired; dry mouth, fruity (acetone) breath; urinating more often, thirst; loss of appetite, nausea or vomiting.

- Patients using an affected pen may want to check their blood sugar level more frequently until receiving a new cartridge holder.

- If patients are in possession of a NovoPen Echo device with a batch number which is not mentioned above, there is no reason for concern and they can be confident that the pen will work as intended.

- Novo Nordisk has received numerous complaints of damaged cartridge holders and has received some reports of adverse events to date.

- Novo Nordisk has corrected this problem and has determined no other component of the pen is affected.

- People using a NovoPen Echo from one of the affected batches listed above are instructed to call Novo Nordisk at **1-855-419-8827** to get a replacement cartridge holder.

- For questions specific to the recall, please call **1-855-419-8827**. For any other general questions or concerns, please contact Novo Nordisk Customer Care at **1-800-727-6500**.