

Fluticasone Nasal Spray – Apotex Corp.

On May 31, 2018 the U.S. Food and Drug Administration (FDA) announced that Apotex Corp. initiated a voluntary recall of one lot of Fluticasone Nasal Spray. This recall is on the following lot: NJ4501. This recall has been initiated as a precautionary measure based on a customer complaint that a bottle had been found to contain small glass particles.

There is a potential for patients to be exposed to the glass particles and mechanical irritation cannot be ruled out. Local trauma to the nasal mucosa might occur with the use of the defective product. To date, Apotex Corp. has not received any reports of adverse events related to recall. Fluticasone Propionate Nasal Spray is indicated for the treatment of seasonal and perennial allergic rhinitis and for the management of sinus pain and pressure associated with allergic rhinitis in patients 4 to 17 years of age. The affected Fluticasone Propionate Nasal Spray can be identified by the information in the table below and on the product label:

| NDC | Lot Number | Expiration Date | Strength | Configuration/Count |
|--------------|------------|-----------------|--|--|
| 60505-0829-1 | NJ4501 | 07/2020 | 50 mcg per spray 120 Metered Sprays | Carton containing 1 Bottle of 50 mcg per spray 120 Metered Sprays |

What You Should Do:

- If you need help to see if your drug has been recalled, call the pharmacy that filled it.
- If you have Fluticasone Nasal Spray from the recalled lot, stop use and contact Apotex Corp. by phone at 1-800-706-5575, 8:30 am to 5:00 pm EST, Monday through Friday.
- If you have medical questions, contact your doctor for guidance.