

Apotex - Recall of fluticasone propionate nasal spray

- On May 31, 2018, the <u>FDA announced</u> the consumer-level recall of one lot of Apotex's <u>fluticasone propionate</u> nasal spray due to small glass particles, which could block the actuator and impact the functionality of the pump.
- The recalled product was distributed nationwide to wholesalers and distributors.

Product Description	NDC #	Lot # (expiration date)
Fluticasone propionate nasal spray, 50 mcg per spray, 120 metered sprays	60505-0829-1	NJ4501 (7/2020)

- Fluticasone propionate nasal spray is indicated for the management of the nasal symptoms of perennial non-allergic rhinitis in adult and pediatric patients aged 4 years and older.
- There is 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 use of the defective product.
 - To date, Apotex has not received any reports of adverse events related to this recall.
- Anyone with existing inventory of the recalled lot should immediately quarantine, discontinue distribution, and arrange for return of the product through GENCO Pharmaceutical Services at 1-877-475-5863.
- Patients should contact their healthcare provider if they have experienced any problems that may be related to using the recalled product.
- For questions regarding this recall, please contact Apotex at 1-800-706-5575.



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