



910 Douglas Pike, Smithfield, RI 02917

6/7/2018

RE: Lot Specific Fluticasone Propionate Nasal Spray Recall due to the presence of small glass particles

In support of safe, informed prescribing, Neighborhood Health Plan of Rhode Island is sharing information about a VOLUNTARY DRUG RECALL with you.

Affected Product:

Product Name	Manufacturer	Affected Lot No.
Fluticasone Propionate Nasal Spray 50mcg per spray 120 metered sprays	Apotex Corporation	NJ4501 exp. July 2020

Reason for Drug Recall:

On 5/31/2018 Apotex Corporation voluntarily recalled one Lot of fluticasone propionate Nasal Spray 50mcg per spray **to the consumer level** because it has been found to contain small glass particles. The glass particles could block the actuator and impact the functionality of the pump. The issue was discovered through a customer complaint. 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 use of the defective product. To date, Apotex Corp. has not received any reports of adverse events related to the recall.

The Manufacturer recommends:

Customers should contact their healthcare provider if they have experienced any problems that may be related to taking or using this drug product.

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

For more information on this drug safety communication, please refer to:

<https://www.fda.gov/safety/medwatch/safetyinformation/safetyalertsforhumanmedicalproducts/ucm609488.htm>

You may also contact the FDA at 1-855-543-3784 (option 4) or via email at druginfo@fda.hhs.gov.

Consumers with questions regarding this recall can contact Apotex Corp. by phone-number 1-800-706-5575 (8:30am – 5:00pm, EST Monday thru Friday) or email address UScustomerservice@Apotex.com.