

**Public Communication
 Important Safety Information on
 Apo-Ciclesonide**

Date: 08/31/2017

Subject: Precautionary Recall of Apo-Ciclesonide

Apotex has initiated a voluntary Type II recall to consumer level for Apo-Ciclesonide Nasal Spray (50mcg/spray) lot numbers NA9667, NC6525 and NE9569 due to the potential for small glass fragments to be released with activation of the Ciclesonide pump, or for the pump mechanism to not activate because it is blocked by glass fragments in the pump. The risk of significant harm to the patient is unlikely, although the presence of glass particles in the nasal cavity may cause abrasion/ irritation. Please see the table below for further information on the impacted lots:

PRODUCT	STRENGTH	DIN	SIZE / FORMAT	Lot Number	EXP. DATE (MM/YYYY)
APO-CICLESONIDE Ciclesonide Nasal Spray	50 µg / metered spray	02417316	120 metered sprays in a bottle	NA9667	12/2018
				NC6525	01/2019
				NE9569	03/2019

Apo-Ciclesonide is a corticosteroid for use in adults and adolescents 12 years of age or older, to relieve the symptoms that may occur with hay fever [seasonal allergic rhinitis (SAR)] or other year-round allergies [perennial allergic rhinitis (PAR)], including stuffiness/congestion in the nose, runny nose, itching and sneezing.

Actions Requested:

Apotex is asking any individuals who have received any of the identified lots of APO-CICLESONIDE (Ciclesonide Nasal Spray, 50 µg /metered spray) to stop using the affected lot and speak with their pharmacist and/or physician and return the affected product to their pharmacy. The consumers can also contact Apotex Inc. via Stericycle by calling at **1-855-215-4940** or by email apotex6029@stericycle.com if they have any question about the recall.

To report a suspected adverse reaction associated with the use of Apo-Ciclesonide 50 µg / metered spray, Nasal Spray patients may contact Apotex by calling **1-800-667-4708** (select prompt 2), by email at drugsafety@apotex.com or by fax at **1-866-429-9133** or **416-401-3819**.

Patients may also report any suspected adverse reactions associated with the use of health products to Health Canada by calling toll free at **1-866-234-2345** or by visiting MedEffect Canada's Web page on Adverse Reaction Reporting to <https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html> for information on how to report online, by mail or by fax.