

NASALCROM- cromolyn sodium spray, metered
Prestige Brands Holdings, Inc.

NasalCrom

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Drug Facts

Active ingredient (per spray)

Cromolyn sodium 5.2mg

Purpose

Nasal allergy symptom controller

Uses

to prevent and relieve nasal symptoms of hay fever and other nasal allergies:

- runny/itchy nose
- sneezing
- allergic stuffy nose

Warnings

Do not use

- if you are allergic to any of the ingredients

Ask a doctor before use if you have

- fever
- discolored nasal discharge
- sinus pain
- wheezing

When using this product

- it may take several days of use to notice an effect. Your best effect may not be seen for 1 to 2 weeks.
- brief stinging or sneezing may occur right after use
- do not use it to treat sinus infection, asthma, or cold symptoms
- do not share this bottle with anyone else as this may spread germs

Stop use and ask a doctor if

- shortness of breath, wheezing, or chest tightness occurs
- hives or swelling of the mouth or throat occurs
- your symptoms worsen
- you have new symptoms
- your symptoms do not begin to improve within two weeks
- you need to use for more than 12 weeks

If pregnant or breast-feeding,

ask a health professional before use.

Keep out of reach of children.

If swallowed, get medical help or contact a Poison Control Center right away. (1-800-222-1222)

Directions

- see package insert on how to use pump
- parent or care provider must supervise the use of this product by young children
- adults and children 2 years and older:
- spray once into each nostril. Repeat 3-4 times a day (every 4-6 hours). If needed, may be used up to 6 times a day.
- use every day while in contact with the cause of your allergies (pollen, molds, pets, and dust)
- to **prevent** nasal allergy symptoms, use before contact with the cause of your allergies. For best results, start using up to one week before contact.
- if desired, you can use this product with other medicines, including other allergy medicines.
- children under 2 years: Do not use unless directed by a doctor

Other information

- store between 20°-25°C (68°-77°F)
- protect from light
- keep carton and package insert. They contain important instructions.
- **do not use if imprinted plastic bottle wrap is broken or missing**
- see bottom panel for lot number and expiration date

Inactive ingredients

benzalkonium chloride, edetate disodium, purified water

Questions or comments?

call **1-877-9-ALLERGY (1-877-925-5374)**

Principal Display Panel

cromolyn sodium nasal solution USP

Nasal Spray

NasalCrom

NASAL ALLERGY SYMPTOM CONTROLLER

Presents and Relieves

Nasal Allergy Symptoms

runny/itchy nose

Without Drowsiness

Full Prescription Strength

Safe for Ages 2 Years & older

100 Metered Sprays

Each spray delivers

5.2 mg cromolyn sodium 0.44 FL AZ (13 mL)



NASALCROM

cromolyn sodium spray, metered

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:52183-199
Route of Administration	NASAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CROMOLYN SODIUM (UNII: Q2WXR110PK) (CROMOLYN - UNII:Y0TK0FS77W)	CROMOLYN SODIUM	5.2 mg

Inactive Ingredients

Ingredient Name	Strength
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
WATER (UNII: 059QF0K00R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:52183-199-14	1 in 1 CARTON		
1		100 in 1 BOTTLE, PUMP		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA075702	10/29/2009	

Labeler - Prestige Brands Holdings, Inc. (159655021)

Establishment

Name	Address	ID/FEI	Business Operations
Bausch & Lomb Inc.		807927397	MANUFACTURE(52183-199)

Revised: 2/2013

Prestige Brands Holdings, Inc.