

CROMOLYN SODIUM- cromolyn sodium spray, metered
Cardinal Health

Cromolyn Sodium Nasal Solution USP
NASAL SPRAY

Active ingredient (per spray)

Cromolyn sodium 5.2 mg

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

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.

Inactive ingredients

benzalkonium chloride, edetate disodium, purified water

Questions?

Serious side effects associated with the use of this product may be reported to 1-800-323-0000.

Before using any medication read all label directions. Keep carton and packaging insert. They contain important information.

Cromolyn Sodium Nasal Solution is convenient and easy to administer using the metered spray pump. See package insert for spray pump directions.

USE ONLY IF BODY SEAL IMPRINTED WITH "Protective Seal" AND YELLOW IS INTACT.

All **Leader**® Brand products are 100% satisfaction guaranteed or return to place of purchase for a full refund.

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CIN 3653011

www.myleader.com 1800-200-6313

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Package/Label Principal Display Panel

Drug Facts

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NDC 37205-223-61



Compare to Nasalcrom® active ingredient*

Cromolyn Sodium Nasal Solution USP
 NASAL SPRAY
 Nasal Allergy Symptom Controller

Prevents and Relieves Nasal Allergy Symptoms:
 ■ runny/itchy nose
 ■ sneezing
 ■ allergic stuffy nose

Without Drowsiness
 Full Prescription Strength

Safe For Ages 2 Years & Older



200 Metered Sprays
 Each spray delivers 5.2 mg cromolyn sodium

0.88 FL OZ (26 mL)

WHAT MAKES CROMOLYN SODIUM NASAL SOLUTION UNIQUE?

Nasal Allergy Symptom Prevention

Cromolyn Sodium Nasal Solution can prevent nasal allergy symptoms when used before exposure to the cause of your nasal allergies, and will build protection against future symptoms as long as you continue to use Cromolyn Sodium Nasal Solution as directed.

Effective Relief

Cromolyn Sodium Nasal Solution provides original prescription-strength relief of nasal allergy symptoms, including congestion, sneezing and runny or itchy nose.

Works Only In Your Nose

Cromolyn Sodium Nasal Solution is a nasal spray that works only in your nose – where nasal allergens attack. It helps to stop the cells in your nose from reacting to pollen, pet dander, and other allergens, so you don't experience nasal allergy symptoms.

SAFE

- No drowsiness
- No jitters
- No "rebound" nasal congestion
- Non habit forming
- Safe to use with other medicines, including other allergy medicines
- Safe to use throughout your allergy season
- Good for year-round allergies
- Safe for children as young as two years old



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NDC 37205-223-61
 LEADER®
 Compare to Nasalcrom® active ingredient*
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 Nasal Allergy Symptom Controller
 Prevents and Relieves Nasal Allergy Symptoms:
 runny/itchy nose
 sneezing
 allergic stuffy nose
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 Full Prescription Strength
 Safe For Ages 2 Years & Older
 SATISFACTION GURANTEED 200 Metered Sprays
 Each spray delivers
 5.2 mg cromolyn sodium

0.88 FL OZ (26 mL)

CROMOLYN SODIUM

cromolyn sodium spray, metered

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:37205-223
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 in 1 mL

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:37205-223-61	1 in 1 CARTON		
1		26 mL in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA075702	07/03/2010	

Labeler - Cardinal Health (097537435)

Establishment

Name	Address	ID/FEI	Business Operations
Bausch & Lomb Incorporated		807927397	MANUFACTURE

Establishment

Name	Address	ID/FEI	Business Operations
Aventis Pharma Manufacturing Pte LTD.		595299306	MANUFACTURE