

**CROMOLYN SODIUM- cromolyn sodium spray, metered**  
**Bausch & Lomb Incorporated**

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**Cromolyn Sodium Nasal Solution, USP**  
**NASAL SPRAY**

***(Adults and children 2 years and older)***

***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***

**For external use only**

**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 (1-800-222-1222) 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.
- see bottom panel for lot number and expiration date

## ***Inactive ingredients***

benzalkonium chloride, edetate disodium, purified water

## ***Questions or comments?***

Call toll-free **1-800-323-0000**

## ***Package/Label Principal Display Panel***

20002627B



Nasal Allergy Symptom Controller  
**NASAL SPRAY**  
**Cromolyn Sodium**  
**Nasal Solution, USP**

**Cromolyn Sodium Nasal Solution, USP NASAL SPRAY**  
 (Adults and children 2 years and older)

**Drug Facts**

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 Cromolyn sodium 5.2 mg.....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**

**For external use only**  
 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**

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 ■ protect from light  
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 ■ see bottom panel for lot number and expiration date

**Drug Facts (continued)**

**Inactive ingredients**  
 boric acid, benzalkonium chloride, edetate disodium, purified water

**Questions or comments?**  
 Call toll-free 1-800-323-0000

Before using any medication read all label directions. Keep carton and package 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.**

**Manufactured by:**  
 Bausch Health Companies Inc.,  
 Laval, Quebec H7L 4A8, Canada  
 HealthGuard is a trademark of  
 Bausch Health Companies Inc. or its affiliates.  
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 or its affiliates Product of Canada

**HealthGuard**

NDC 57782-397-26

**Cromolyn  
 Sodium Nasal  
 Solution, USP**  
**NASAL SPRAY**

Nasal Allergy Symptom Controller  
 For intranasal use only.

*Prevents and Relieves  
 Nasal Allergy Symptoms:*

- runny/itchy nose
- sneezing
- allergic stuffy nose

Original Prescription Strength

Safe For Ages 2+

**200 Metered Sprays**

Each spray delivers 5.2 mg cromolyn sodium

**0.88 FL OZ (26 mL)**

**How Does  
 Cromolyn Sodium  
 Nasal Solution Work?**

Cromolyn Sodium Nasal Solution helps to stop the cells in your nose from reacting to nasal allergens - including pollen & pet dander when used as directed.

**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 non-steroidal, original prescription-strength relief of nasal allergy symptoms, including congestion, sneezing and runny or itchy nose.

**SAFE**

- Safe for children as young as 2 years old
- No drowsiness
- No jitter
- No "rebound" nasal congestion
- Safe to use with other medicines, including other allergy medicines
- Good for year-round allergies



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**HealthGuard**

NDC 57782-397-26

**Cromolyn  
 Sodium Nasal  
 Solution, USP**

**NASAL SPRAY**

Nasal Allergy Symptom Controller  
**For intranasal use only.**

***Prevents and Relieves  
Nasal Allergy Symptoms:***

- **runny/itchy nose**
- **sneezing**
- **allergic stuffy nose**

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Each spray delivers 5.2 mg cromolyn sodium

0.88 FL OZ (26 mL)

## **CROMOLYN SODIUM**

cromolyn sodium spray, metered

### **Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:57782-397
<b>Route of Administration</b>	NASAL		

### **Active Ingredient/Active Moiety**

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<b>CROMOLYN SODIUM</b> (UNII: Q2WXR1I0PK) (CROMOLYN - UNII:Y0TK0FS77W)	CROMOLYN SODIUM	5.2 mg

### **Inactive Ingredients**

<b>Ingredient Name</b>	<b>Strength</b>
<b>BENZALKONIUM CHLORIDE</b> (UNII: F5UM2KM3W7)	
<b>EDETATE DISODIUM</b> (UNII: 7FLD91C86K)	
<b>WATER</b> (UNII: 059QF0KO0R)	

### **Packaging**

<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:57782-397-26	1 in 1 CARTON	07/03/2001	
1		200 in 1 BOTTLE; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)		

### **Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA075702	07/03/2001	

**Labeler** - Bausch & Lomb Incorporated (196603781)

### Establishment

Name	Address	ID/FEI	Business Operations
Bausch Health Companies, Inc.		245141858	MANUFACTURE(57782-397)

Revised: 6/2021

Bausch & Lomb Incorporated