

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

Drug Facts

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

9226205

Principal Display Panel

NASAL SPRAY

NasalCrom[®]

cromolyn sodium nasal solution, USP

NASAL ALLERGY

SYMPTOM CONTROLLER

PREVENTS & RELIEVES

NASAL ALLERGY
SYMPTOMS

For Intranasal use only.

- 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)

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 NASAL ALLERGY
 Cromolyn sodium nasal solution, USP

NasalCrom[®]

NASAL SPRAY

NasalCrom[®] Nasal Spray:
 (Adults and children 2 years and older)

Drug Facts

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.

Drug Facts (continued)

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

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



NasalCrom[®] nasal spray 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.



NASAL SPRAY

NasalCrom[®]

cromolyn sodium nasal solution, USP

NASAL ALLERGY
 SYMPTOM CONTROLLER

PREVENTS & RELIEVES NASAL ALLERGY SYMPTOMS

For intranasal use only.

- 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 NasalCrom[®] Work?

NasalCrom[®] contains Cromolyn Sodium which 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

NasalCrom[®] nasal spray 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 NasalCrom[®] nasal spray as directed.

EFFECTIVE RELIEF

NasalCrom[®] nasal spray 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 jittery
- No "rebound" nasal congestion
- Safe to use with other medicines, including other allergy medicines
- Good for year-round allergies

Dist. by: Mediatech Products, Inc.
 Tarrytown, NY 10591
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 NCU5001101 Product of Italy
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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: Q2WXR1I0PK) (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	10/29/2009	
1		100 in 1 BOTTLE, PUMP; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)		
2	NDC:52183-199-13	1 in 1 CARTON	10/29/2009	
2		200 in 1 BOTTLE, PUMP; 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		10/29/2009	

Labeler - Prestige Brands Holdings, Inc. (159655021)

Establishment

Name	Address	ID/FEI	Business Operations
Bausch Health Companies Inc.		245141858	manufacture(52183-199)

Revised: 12/2023

Prestige Brands Holdings, Inc.