BUDESONIDE- budesonide spray, metered Apotex Corp.

Drug Facts

Active ingredient (in each spray)

Budesonide (glucocorticoid) 32 mcg

Purpose

Nasal allergy symptom reliever

Uses

Temporarily relieves these symptoms of hay fever or other upper respiratory allergies:

• nasal congestion • runny nose • itchy nose • sneezing

Warnings

Do not use

- in children under 6 years of age
- if you have ever had an allergic reaction to any of the ingredients

Ask a doctor before use if you

- have had recent nose ulcers or nose surgery
- have had a nose injury that has not healed
- are using a steroid medicine for asthma, allergies or skin rash
- have an eye infection
- have or had glaucoma or cataracts

When using this product

- the growth rate of some children may be slower
- some symptoms may get better on the first day of treatment. It may take up to two weeks of daily use to feel the most symptom relief.
- do not share this bottle with anyone else as this may spread germs
- remember to tell your doctor about all the medicines you take, including this one

Stop use and ask a doctor if

- you have, or come into contact with someone who has, chickenpox, measles or tuberculosis
- you have or develop symptoms of an infection such as persistent fever
- you have any change in vision
- you have severe or frequent nosebleeds

If pregnant or breast-feeding, ask a health professional before use.

Keep out of reach of children.

In case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222).

Directions

Read insert (inside package) on how to:

- get a new bottle ready (primed) before first use
- prime bottle again if not used for two days
- use the spray
- clean the spray nozzle

ADULTS AND CHILDREN 12 YEARS OF AGE AND OLDER

- adults and children
 once daily, spray 2 times into each nostril while sniffing gently
 once your allergy symptoms
- once your allergy symptoms of age and older • once your allergy symptoms improve, reduce to 1 spray in each nostril per day

CHILDREN 6 TO UNDER 12 YEARS OF AGE

- the growth rate of some children may be slower while using this product. Talk to your child's doctor if your child needs to use the spray for longer than two months a year
 - an adult should supervise use
 - once daily, spray 1 time into each nostril while sniffing gently

children 6 to

- if allergy symptoms do not
- under 12 years of age allergy symptoms improve, reduce to 1 spray in each

nostril per day

children

under 6 • do not use years of age

- do not use more than directed
- if you forget a dose, do **not** double the

next dose

- do not spray into eyes or mouth
- if allergy symptoms do not improve after two weeks, stop using and talk to a doctor
- do not use for the common cold
- shake well before each use

Other information

- do not use if the safety seal labeled "sealed for your protection" is broken or missing.
- keep package and insert. They contain important information.
- store at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature]. Do not freeze. Protect from light.

Inactive ingredients

carboxymethyl cellulose sodium, dextrose anhydrous, edetate disodium dihydrate, hydrochloric acid (for pH adjustment), microcrystalline cellulose, polysorbate 80, potassium sorbate, purified water

Questions or comments?

call toll free **1-800-706-5575**

Principal Display Panel - Carton

CARTON LABEL - PRINCIPAL DISPLAY PANEL - 32 mcg per spray

APOTEX CORP. NDC 60505-6129-2

Budesonide Nasal Spray

Allergy Spray

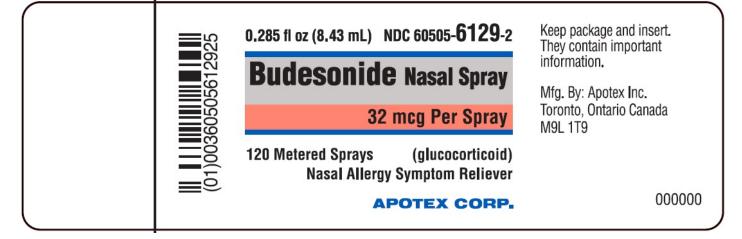
120 sprays

Relief of:

- Nasal Congestion
- Runny Nose
- Itchy Nose
- Sneezing



Principal Display Panel - Bottle BOTTLE LABEL - PRINCIPAL DISPLAY PANEL - 32 mcg per spray APOTEX CORP. NDC 60505-6129-2 Budesonid Nasal Spray Allergy Spray



B	UDESON	NIDE					
		pray, metered					
Ρ	roduct In	formation					
Ρ	roduct Type	9	HUMAN OTC DRUG	Item Code (Source) NDC:605		05-6129	
R	oute of Adr	ninistration	NASAL				
A	ctive Ingr	edient/Active	Moiety				
		Ingredient Name Basis of Strength				rength	Strength
B	BUDESONIDE (UNII: Q3OKS62Q6X) (Budesonide - UNII:Q3OKS62			S62Q6X)	BUDESONIDE		32 ug
Ir	active In	gredients					
			Ingredient Nam	e			Strength
EDETATE DISODIUM (UNII: 7FLD91C86K)							
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED FORM (UNII: K6790BS311)							
			E (UNII: OP1R32D61U)				
			I (UNII: IY9XDZ 35W2)				
		ORBATE (UNII: 1VP 80 (UNII: 60ZP39)					
		IC ACID (UNII: QTT:					
	ATER (UNII: 0		1,902007				
P	ackaging						
#	ltem Code		Package Description	1	Marketin Start Da	-	larketing ind Date
1	NDC:60505- 6129-2	1 in 1 BOTTLE, SP	RAY		04/19/2016		
1		120 in 1 BOTTLE, 9 Device/System (sy	SPRAY; Type 2: Prefilled Dr rringe, patch, etc.)	ug Delivery			
2	NDC:60505- 6129-7	3 in 1 CARTON			04/19/2016		

		ANDA078949	04/19/2016		
Marketing Category			Marketing Start Date	Marketing End Date	
Μ	larketin	g Information			
3		120 in 1 BOTTLE, SPRAY; Type 2: Prefilled Drug Deliv Device/System (syringe, patch, etc.)	ery		
3	NDC:60505- 6129-6	2 in 1 CARTON	04/19/2016		
2		120 in 1 BOTTLE, SPRAY; Type 2: Prefilled Drug Deliv Device/System (syringe, patch, etc.)	ery		

Labeler - Apotex Corp. (845263701)

Revised: 11/2023

Apotex Corp.