BUDESONIDE- budesonide spray, metered
Topco Associates LLC

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 12 years of age and older	• once daily, spray 2 times into each nostril while sniffing gently • 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

children 6 to under 12 years of age	• an adult should supervise use • once daily, spray 1 time into each nostril while sniffing gently • if allergy symptoms do not improve, increase to 2 sprays in each nostril per day. Once allergy symptoms improve, reduce to 1 spray in each nostril per day
children under 6 years of age	• do not use

- **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 carton is opened, torn or broken or shows any signs of tampering.**
- 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

TopCare NDC 36800-113-01

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

TopCare NDC 36800-113-01

Budesonide Nasal Spray

Allergy Spray

120 sprays

BUDESONIDE

budesonide spray, metered

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:36800-113
Route of Administration	NASAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
Budesonide (UNII: Q3OKS62Q6X) (Budesonide - UNII:Q3OKS62Q6X)	Budesonide	32 ug

Inactive Ingredients	
Ingredient Name	**Strength**
EDETATE DISODIUM (UNII: 7FLD91C86K)	
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED FORM (UNII: K679OBS311)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
DEXTROSE, UNSPECIFIED FORM (UNII: IY9XDZ35W2)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
HYDROCHLORIC ACID (UNII: QTT17582CB)	
WATER (UNII: 059QF0KO0R)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:36800-113-01	1 in 1 BOTTLE, SPRAY	08/31/2016	
1		120 in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date

ANDA	ANDA078949	08/31/2016	

Labeler - Topco Associates LLC (006935977)

Registrant - Apotex Inc. (209429182)

Establishment

Name	Address	ID/FEI	Business Operations
Apotex Inc.		255092496	analysis(36800-113) , manufacture(36800-113)

Establishment

Name	Address	ID/FEI	Business Operations
Legacy Pharmaceutical Packaging		143213275	pack(36800-113)

Revised: 2/2020 Topco Associates LLC