

# **BUDESONIDE- budesonide spray, metered**

## **Rugby Laboratories**

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### **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 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 60ms**

**CARTON LABEL - PRINCIPAL DISPLAY PANEL - 32 mcg per spray**

**Rugby Laboratories NDC 0536-1112-40**

**Budesonide Nasal Spray**

**Allergy Spray**

**60 sprays**

**Relief of:**

- Nasal Congestion
- Runny Nose
- Itchy Nose
- Sneezing



Aqueous Free Area  
40 mm x 40 mm  
for placement of Lot & Exp.

WARRANTY: DO NOT USE IF THE  
SAFETY SEAL LABELED "SEALED FOR YOUR  
PROTECTION" IS BROKEN OR MISSING.

ING 073E-0

NDC 0536-1112-40



# Budesonide Nasal Spray

(glucocorticoid)  
32 mcg Per Spray

## Nasal Allergy Symptom Reliever

### Relief of:

- Nasal Congestion
- Runny Nose
- Itchy Nose
- Sneezing



**60**  
METERED  
SPRAYS  
0.149 fl oz (5 mL)

### Drug Facts

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Budesonide (glucocorticoid) 32 mcg..... 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**  
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 If you have ever had an allergic reaction to any of the ingredients

**Ask a doctor before use if you**  
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 have had a nose injury that has not healed  
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 have an eye infection  
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 you have, or come into contact with someone who has chickenpox, measles or tuberculosis  
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### Drug Facts (continued)

- you have any change in vision
- you have severe or frequent nosebleeds

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**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

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- children 6 to under 12 years of age
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  - once daily, spray 1 time into each nostril while sniffing gently

### Drug Facts (continued)

- 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
- do not use

children under 6 years of age

- do not use more than directed
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### Inactive ingredients

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### Questions or comments?

call toll free 1-800-706-5575

**Important: Read all product information before using. Keep package and insert. They contain important information.**

**Distributed by:**  
 RUGBY LABORATORIES  
 17177 N LAUREL PARK DRIVE, SUITE 233  
 LYNONIA, MI 48152, USA  
 www.rugbylaboratories.com  
 MADE IN CANADA

**RE-ORDER NO.**  
370498

**R-70 10/16**



**Principal Display Panel - Carton 120ms**  
**CARTON LABEL - PRINCIPAL DISPLAY PANEL - 32 mcg per spray**  
**Rugby Laboratories NDC 0536-1112-48**

## **Budesonide Nasal Spray**

### **Allergy Spray**

**120 sprays**

#### **Relief of:**

- Nasal Congestion
- Runny Nose
- Itchy Nose
- Sneezing



**Principal Display Panel - Bottle 60ms**

**BOTTLE LABEL - PRINCIPAL DISPLAY PANEL - 32 mcg per spray**

**Rugby Laboratories NDC 0536-1112-40**

**Budesonide Nasal Spray**

**Allergy Spray**

60 sprays



Principal Display Panel - Bottle 120ms

**BOTTLE LABEL - PRINCIPAL DISPLAY PANEL** - 32 mcg per spray

**Rugby Laboratories** NDC 0536-1112-48

**Budesonide Nasal Spray**

**Allergy Spray**

120 sprays



## BUDESONIDE

budesonide spray, metered

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0536-1112
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
<b>EDETATE DISODIUM</b> (UNII: 7FLD91C86K)	
<b>CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED</b> (UNII: K679OBS311)	
<b>MICROCRYSTALLINE CELLULOSE</b> (UNII: OP1R32D61U)	
<b>DEXTROSE, UNSPECIFIED FORM</b> (UNII: IY9XDZ35W2)	
<b>POTASSIUM SORBATE</b> (UNII: 1VPU26JZZ4)	
<b>POLYSORBATE 80</b> (UNII: 6OZP39ZG8H)	
<b>HYDROCHLORIC ACID</b> (UNII: QTT17582CB)	
<b>WATER</b> (UNII: 059QF0K00R)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0536-1112-40	1 in 1 CARTON	07/20/2016	
1		60 in 1 BOTTLE, SPRAY; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)		
2	NDC:0536-1112-48	1 in 1 CARTON	07/20/2016	
2		120 in 1 BOTTLE, SPRAY; 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	ANDA078949	07/13/2016	

**Labeler** - Rugby Laboratories (079246066)

**Registrant** - Apotex Inc. (209429182)

## Establishment

Name	Address	ID/FEI	Business Operations
Apotex Inc.		255092496	analysis(0536-1112) , manufacture(0536-1112)

Revised: 12/2023

Rugby Laboratories