

BUDESONIDE- budesonide spray, metered

Rugby Laboratories

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
- sneezing
- itchy nose

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 (1-800-222-1222) right away.

Direction

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	<ul style="list-style-type: none"> • 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
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CHILDREN 6 YEARS 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 month

children 6 to under 12 years of age	<ul style="list-style-type: none"> • 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
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children under 6 years of age	<ul style="list-style-type: none"> • do not use
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- **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 seals are broken**
- keep the package and insert. They contain important information.
- store upright 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 **1-877-753-3935** Monday-Friday 9AM-5PM EST

Principal Display Panel

budesonide

nasal spray

budesonide (glucocorticoid)

32 mcg per spray

nasal allergy

symptom reliever

original prescription strength

24-hours relief of:

- nasal congestion
- runny nose
- itchy nose
- sneezing

non-drowsy

↑ store upright ↑

metered sprays

fl oz (mL)

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

TAMPER EVIDENT: DO NOT USE IF CARTON SEALS ARE BROKEN.

Distributed by:

RUGBY® LABORATORIES


Indianapolis, IN 46268

(800) 616-2471

www.major-rugby.com

Product of Italy

Package label

NDC 0536-1466-84

budesonide nasal spray

budesonide (glucocorticoid) 32 mcg per spray
nasal allergy symptom reliever

original prescription strength

24-hour relief of:

- nasal congestion
- runny nose
- itchy nose
- sneezing

non-drowsy

↑ store upright ↑

120 metered sprays
0.285 fl oz (8.43 mL)

Drug Facts

Active ingredient (in each spray) Budesonide (glucocorticoid) 32 mcg	Purpose Nasal allergy symptom reliever
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Uses
Temporarily relieves these symptoms of hay fever or other upper respiratory allergies:

- nasal congestion
- runny nose
- sneezing
- itchy nose

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

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- 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

Drug Facts (continued)
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

Drug Facts (continued)

- 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 seals are broken
- keep the package and insert. They contain important information.
- store upright 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 1-877-753-3636 Monday-Friday 9AM-5PM EST


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


TAMPER EVIDENT: DO NOT USE IF CARTON SEALS ARE BROKEN.

Distributed by:
RUGBY® LABORATORIES
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(800) 616-2471
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Product of Italy

PLD-A304A FC009476
Rev. 06/25 R-5B Re-order No. 371251


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RUGBY Nasal Spray



Nasal Spray

BUDESONIDE

budesonide spray, metered

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0536-1456
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 (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:0536-1456-84	1 in 1 CARTON	12/01/2025	
1		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	12/01/2025	

Labeler - Rugby Laboratories (079246066)

Revised: 12/2025

Rugby Laboratories