

**TRIAMCINOLONE ACETONIDE- triamcinolone acetonide spray, metered
Apotex Corp.**

Drug Facts

Active ingredient (in each spray)

Triamcinolone acetonide 55 mcg (glucocorticoid)

Purpose

Allergy symptom reliever

Uses

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

- nasal congestion
- runny nose
- sneezing
- itchy nose

Warnings

For external use only

Do not use

- In children under 2 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 one week 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 in contact with someone who has, chickenpox, measles or tuberculosis
- you have or develop symptoms of an infection such as persist 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.

Directions

Read insert (inside package) on how to:

- **get a new bottle ready (primed) before first use**
- **prime bottle again if not used for more than 2 weeks**
- **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
CHILDREN 2 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 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 2 to under 6 years of age	◦ an adult should supervise use
	◦ once daily, spray 1 time into each nostril while sniffing gently
children under 2 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 one week, stop using and talk to a doctor
- do not use for the common cold

- shake well before each use

Other information

- TAMPER EVIDENT: DO NOT USE IF SEALS ON CARTON ARE BROKEN OR MISSING
- Store between 20°C to 25°C (68°F to 77°F)

Inactive ingredients

benzalkonium chloride solution (50% W/V) dextrose monohydrate, edetate disodium dihydrate, hydrochloric acid, microcrystalline cellulose, polysorbate 80 purified water & sodium hydroxide

Questions or comments?

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

Principal Display Panel


Triamcinolone Acetonide Nasal Spray, USP

55 mcg per spray

allergy symptom reliever (glucocorticoid)

120 MD per spray

NDC 60505-6275-7

		NDC 60505-6275-7	
TRIAMCINOLONE ACETONIDE Nasal Spray, USP		IMPORTANT: Read and keep carton and insert for complete warnings, directions and other important information.	
55 mcg per spray Allergy symptom reliever (glucocorticoid)		CHILDREN 2 TO UNDER 12 YEARS OF AGE: Talk to your child's doctor if your child needs to use the spray for longer than two months a year.	
120 Sprays 0.57 fl. oz. (16.9 mL)		Keep out of reach of children.	
		Store between 20°C to 25°C (68°F to 77°F). Shake well before each use.	
		Questions or comments? Call toll-free 1-800-706-5575	
		Manufactured by: Apotex Inc. Toronto, Ontario, Canada M9L 1T9 Manufactured for: Apotex Corp., Weston, Florida, 33326	
		461719	



TRIAMCINOLONE ACETONIDE

triamcinolone acetonide spray, metered

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:60505-6275
Route of Administration	NASAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TRIAMCINOLONE ACETONIDE (UNII: F446C597KA) (Triamcinolone Acetonide - UNII:F446C597KA)	TRIAMCINOLONE ACETONIDE	55 ug

Inactive Ingredients

Ingredient Name	Strength
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7)	
DEXTROSE MONOHYDRATE (UNII: LX22YL083G)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
HYDROCHLORIC ACID (UNII: QTT17582CB)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
WATER (UNII: 059QF0KO0R)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED (UNII: K679OBS311)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:60505-6275-7	1 in 1 CARTON	01/26/2024	
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	ANDA214615	01/26/2024	

Labeler - Apotex Corp. (845263701)