TRIAMCINOLONE ACETONIDE- triamcinolone acetonide spray, metered
CARDINAL HEALTH 110, LLC. DBA LEADER

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 upper respiratory allergies:

- nasal congestion
- runny nose
- sneezing
- itchy nose

Warnings

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 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.

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 per day.
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**
- keep package and insert, They contain important information.
- Store between 20ºC to 25ºC (68ºF to 77ºF)

Inactive ingredients

benzalkonium chloride solution (50% W/V) carboxymethylcellulose sodium, 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

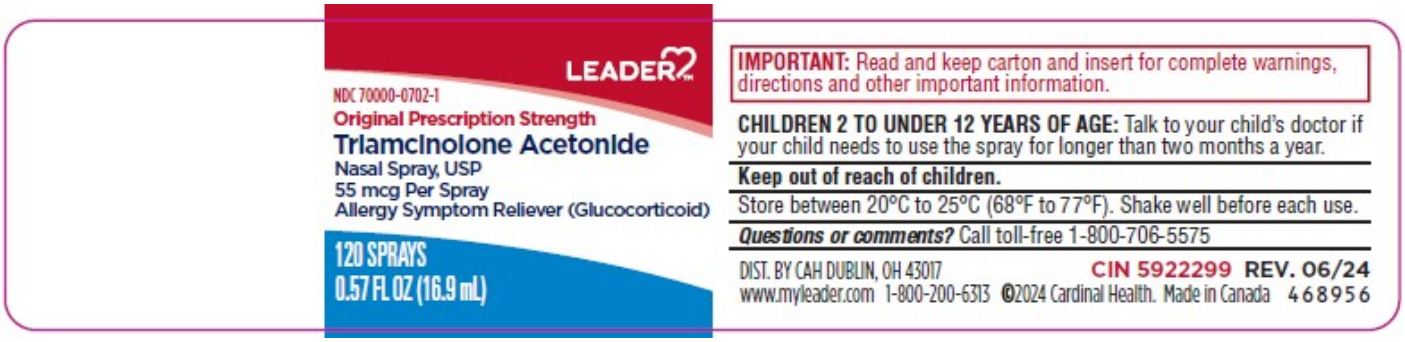
Triamcinolone Acetonide Nasal Spray, USP

55 mcg per spray

allergy symptom reliever(glucocorticoid)

120 MD per spray

NDC 70000-0702-1



TRIAMCINOLONE ACETONIDE

triamcinolone acetonide spray, metered

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:70000-0702
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:70000-0702-1	1 in 1 CARTON	06/05/2024	
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	06/05/2024	

Labeler - CARDINAL HEALTH 110, LLC. DBA LEADER (063997360)

Revised: 9/2024 CARDINAL HEALTH 110, LLC. DBA LEADER