

**LEADER NASAL ALLERGY- triamcinolone acetonide spray, metered
Praxis, LLC**

Leader Nasal Allergy Spray 24 Hour 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

- 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 into contact with someone who has, chickenpox, measles or tuberculosis
- you have or develop symptoms of an infection such as a 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 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	<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
CHILDREN 2 TO UNDER 12 YEARS OF AGE	
<ul style="list-style-type: none"> • 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	<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.
children 2 to under 6 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
children under 2 years of age	<ul style="list-style-type: none"> • 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

- **do not use if printed bottle wrap is torn or opened**
- keep package and insert. They contain important information.
- store between 20 °-25 °C (68 °-77 °F)

Inactive ingredients

benzalkonium chloride, carboxymethylcellulose sodium, dextrose anhydrous, edetate disodium dihydrate, hydrochloric acid or sodium hydroxide (for pH adjustment), microcrystalline cellulose, polysorbate 80, purified water

Questions or comments?

1-800-719-9260

Consumer information

Triamcinolone Acetonide Nasal Spray 55 mcg per spray

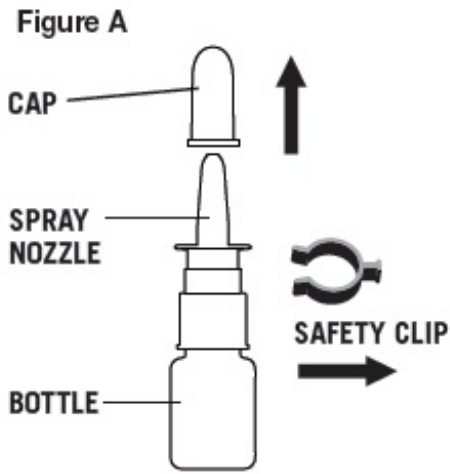
IMPORTANT INFORMATION

- **Read both sides of this insert** for complete instructions on how to get a bottle ready (primed), how to use the spray bottle and how to clean the spray nozzle.
- Keep this insert as it contains important information.

STEPS TO GET A NEW BOTTLE READY FOR USE (PRIMED)

1. Before first use, a new bottle must be primed.

1. Remove cap and safety clip (*Figure A*).
2. Shake bottle.
3. Press and release spray nozzle until a fine mist is produced (*as shown in Figure B*). This may take several times. Take care not to spray in face.

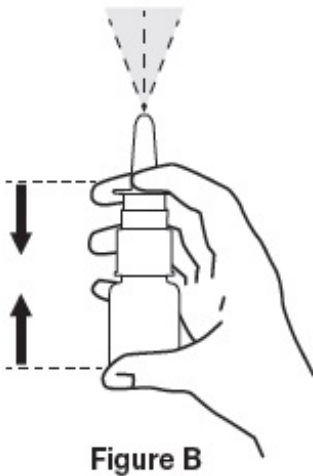


PRIME BOTTLE AGAIN IF NOT USED FOR MORE THAN 2 WEEKS

- Repeat steps for priming a bottle (see above).

USE INSTRUCTIONS

1. Blow nose gently to clear nostrils.
2. Remove cap and safety clip, then shake bottle.
3. Hold bottle with thumb under bottle and spray nozzle between fingers (as shown in Figure B).
4. Press against the outside of your nose with your finger to close off one nostril (as shown in Figure C).
5. Place the tip of the spray nozzle into the other nostril. The spray nozzle should not reach far into the nose. Aim nozzle toward back of nose (as shown in Figure C).



DO NOT spray toward nasal septum (the wall between the 2 nostrils) (as shown in Figure D).

Figure C



Figure D



1. 6. While sniffing gently, spray into nostril.

IMPORTANT: For complete dosing instructions, See “Directions for use” on next side.

1. 7. Repeat steps “4” through “6” for the other nostril.
2. 8. After using the nasal spray, wipe nozzle with a tissue, replace safety clip, and replace cap by pressing it down over the spray nozzle.

NOTE: Avoid blowing nose for 15 minutes after use.

If nozzle does not spray properly, see cleaning instructions on next side.

(continued on side 2)

SIDE 1

DIRECTIONS FOR USE

<ul style="list-style-type: none"> • BEFORE first use, you must get a new bottle ready (primed). • If bottle is not used for more than 2 weeks, prime bottle again. 	
Dosing	
ADULTS AND CHILDREN 12 YEARS OF AGE AND OLDER	
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	allergy symptoms improve, reduce to 1 spray in each nostril per day.
children 2 to under 6 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
children under 2 years of age	<ul style="list-style-type: none"> • do not use
Other important information for use	
<ul style="list-style-type: none"> • <i>Do not use more than directed.</i> • <i>If you forget a dose, do not double the next dose.</i> • <i>Do not spray into eyes or mouth.</i> • <i>If you get the spray in your eyes, rinse well with water.</i> • <i>If allergy symptoms do not improve after one week, stop using and talk to a doctor.</i> • <i>Do not share this bottle with anyone else as this may spread germs.</i> 	

IF PUMP DOES NOT SPRAY PROPERLY, THE NOZZLE MAY BE BLOCKED

1. Never try to unblock nozzle with a pin or any other object (*as shown in Figure E*).
2. Clean the nozzle as shown below.

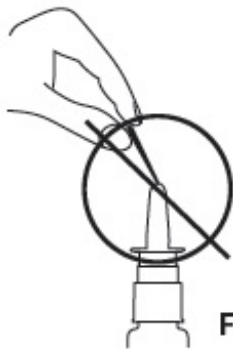
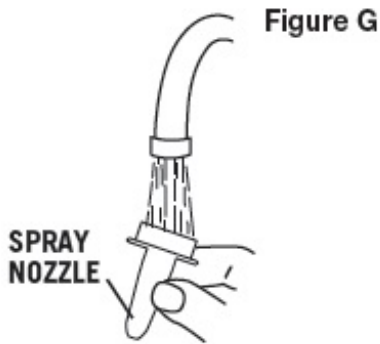
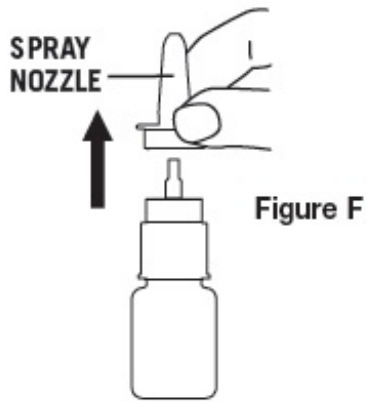


Figure E

CLEANING INSTRUCTIONS

1. Gently pull spray nozzle away from bottle (*as shown in Figure F*).
2. Rinse **SPRAY NOZZLE ONLY** under warm water (*as shown in Figure G*).
3. Shake or tap to remove excess water.
4. Re-attach spray nozzle to bottle.
5. Press and release spray nozzle until a fine spray is produced, taking care not to spray in face.



Triamcinolone Acetonide Nasal Spray pump is now ready to use.

Where can I get more information? 1-800-719-9260

Store between 20°-25°C (68°-77°F)

Made in Israel

Distributed By

Perrigo®

Allegan, MI 49010

SIDE 2

: 44300 00 J4

Package/Label Principal Display Panel

LEADER™

Multi-Symptom

Nasal Allergy Spray 24 Hour

Triamcinolone Acetonide Nasal Spray, 55 mcg per spray

Allergy Symptom Reliever (Glucocorticoid)*

Original Prescription Strength

24 HR Relief of: Nasal Congestion, Sneezing, Runny Nose, Itchy Nose

COMPARE TO NASACORT® ALLERGY 24HR active ingredient

Scent-Free

Non-Drowsy

Alcohol-Free

100% Money Back Guarantee

*Triamcinolone acetonide is a steroid medicine known as a glucocorticoid.

0.57 FL OZ (16.9 mL) 120 SPRAYS



LEADER NASAL ALLERGY

triamcinolone acetonide spray, metered

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:59368-204

Route of Administration	NASAL
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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)	
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED FORM (UNII: K679OBS311)	
ANHYDROUS DEXTROSE (UNII: 5SL0G7R0OK)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
HYDROCHLORIC ACID (UNII: QTT17582CB)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
WATER (UNII: 059QF0KOOR)	

Product Characteristics

Color	white (off white)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59368-204-01	1 in 1 CARTON	12/15/2016	
1		120 in 1 BOTTLE; 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	ANDA078104	12/15/2016	

Labeler - Praxis, LLC (016329513)

Establishment

Name	Address	ID/FEI	Business Operations
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Revised: 1/2023

Praxis, LLC