

**TRIAMCINOLONE ACETONIDE NASAL- triamcinolone acetonide spray,  
metered  
Praxis, LLC**

-----  
**Padagis Nasal Spray 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 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**

<b>ADULTS AND CHILDREN 12 YEARS OF AGE AND OLDER</b>	
<b>adults and children 12 years of age and older</b>	<ul style="list-style-type: none"> <li>• once daily, spray 2 times into each nostril while sniffing gently</li> <li>• once your allergy symptoms improve, reduce to 1 spray in each nostril per day</li> </ul>
<b>CHILDREN 2 TO UNDER 12 YEARS OF AGE</b>	
<ul style="list-style-type: none"> <li>• 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.</li> </ul>	
<b>children 6 to under 12 years of age</b>	<ul style="list-style-type: none"> <li>• an adult should supervise use</li> <li>• once daily, spray 1 time into each nostril while sniffing gently</li> <li>• 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.</li> </ul>
<b>children 2 to under 6 years of age</b>	<ul style="list-style-type: none"> <li>• an adult should supervise use</li> <li>• once daily, spray 1 time into each nostril while sniffing gently</li> </ul>
<b>children under 2 years of age</b>	<ul style="list-style-type: none"> <li>• <b>do not use</b></li> </ul>
<ul style="list-style-type: none"> <li>• <b>do not use more than directed</b></li> <li>• if you forget a dose, do <b>not</b> double the next dose</li> <li>• do not spray into eyes or mouth</li> <li>• if allergy symptoms do not improve after one week, stop using and talk to a doctor</li> <li>• do not use for the common cold</li> <li>• shake well before each use</li> </ul>	

## 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

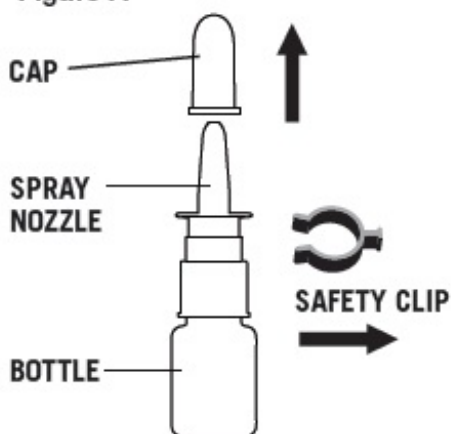
- **Read both sides of this insert** for complete instructions on how to get a bottle ready (primed), how to use the spray bottle and how to clean the spray nozzle.
- Keep this insert as it contains important information.

#### 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.

Figure A

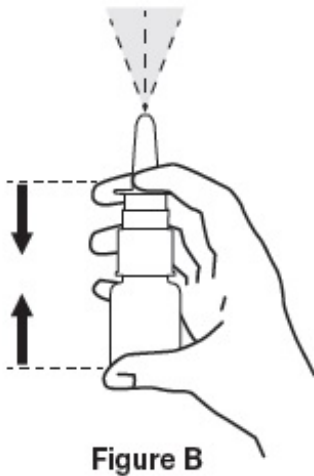


**PRIME BOTTLE AGAIN IF NOT USED FOR MORE THAN 2 WEEKS**

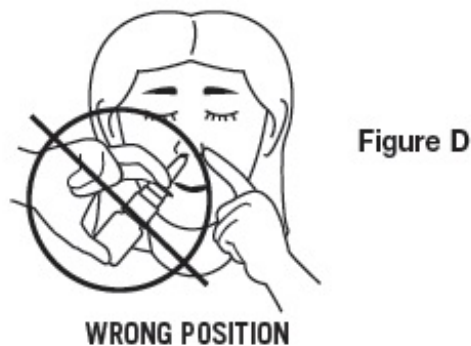
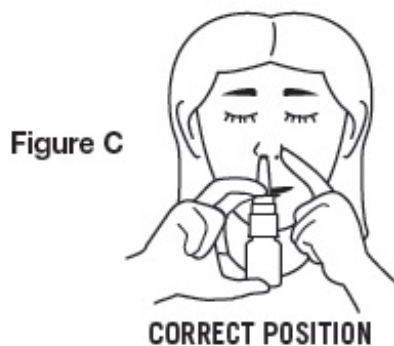
- Repeat steps for priming a bottle (see above).

## 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).



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

germs.

### **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.

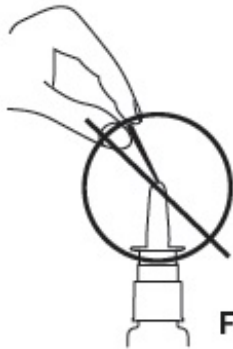


Figure E

### **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.

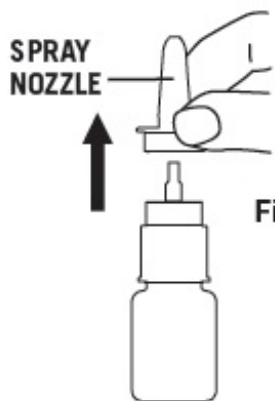
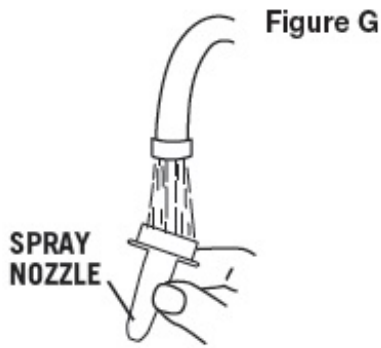


Figure F



***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 J5

### **Package/Label Principal Display Panel**

Compare to Nasacort® Allergy 24HR

active ingredient

Multi-Symptom Triamcinolone Acetonide Nasal Spray

55 mcg per spray

Allergy Symptom Reliever (Glucocorticoid)\*

24 Hour Relief of:

- Nasal Congestion
- Sneezing
- Runny Nose
- Itchy Nose

Original Prescription Strength

NON DROWSY

SCENT FREE

ALCOHOL FREE

120 SPRAYS

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

0.57 FL OZ (16.9 mL)

Padagis™



TRIAMCINOLONE ACETONIDE NASAL			
triamcinolone acetonide spray, metered			
<b>Product Information</b>			
<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:59368-202
<b>Route of Administration</b>	NASAL		
<b>Active Ingredient/Active Moiety</b>			



Ingredient Name		Basis of Strength	Strength	
<b>TRIAMCINOLONE ACETONIDE</b> (UNII: F446C597KA) (TRIAMCINOLONE ACETONIDE - UNII:F446C597KA)		TRIAMCINOLONE ACETONIDE	55 ug	
<b>Inactive Ingredients</b>				
Ingredient Name			Strength	
<b>BENZALKONIUM CHLORIDE</b> (UNII: F5UM2KM3W7)				
<b>CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED</b> (UNII: K679OBS311)				
<b>ANHYDROUS DEXTROSE</b> (UNII: 5SL0G7R0OK)				
<b>EDETATE DISODIUM</b> (UNII: 7FLD91C86K)				
<b>HYDROCHLORIC ACID</b> (UNII: QTT17582CB)				
<b>SODIUM HYDROXIDE</b> (UNII: 55X04QC32I)				
<b>MICROCRYSTALLINE CELLULOSE</b> (UNII: OP1R32D61U)				
<b>POLYSORBATE 80</b> (UNII: 6OZP39ZG8H)				
<b>WATER</b> (UNII: 059QF0K00R)				
<b>Product Characteristics</b>				
<b>Color</b>	white (off white)	<b>Score</b>		
<b>Shape</b>		<b>Size</b>		
<b>Flavor</b>		<b>Imprint Code</b>		
<b>Contains</b>				
<b>Packaging</b>				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59368-202-01	1 in 1 CARTON	03/28/2017	
1		120 in 1 BOTTLE; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)		
2	NDC:59368-202-02	3 in 1 PACKAGE	03/28/2017	
2		1 in 1 CARTON; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)		
<b>Marketing Information</b>				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
ANDA	ANDA078104	03/28/2017		

**Labeler** - Praxis, LLC (016329513)

### Establishment

Name	Address	ID/FEI	Business Operations
Praxis, LLC		016329513	manufacture(59368-202) , pack(59368-202) , label(59368-202)

