TRIAMCINOLONE ACETONIDE NASAL- triamcinolone acetonide spray, metered Bryant Ranch Prepack

Triamcinolone Acetonide 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

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 					
CI	HILDREN 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 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 ge if allergy symptoms do not improve, increase to 2 sprays 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 gent 					
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

- 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

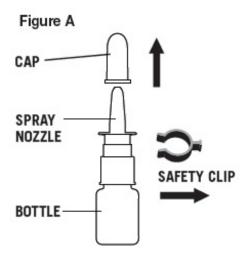
IMPORTANT INFORMATION

- **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.

- a. Remove cap and safety clip (Figure A).
- b. Shake bottle.
- c. 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.

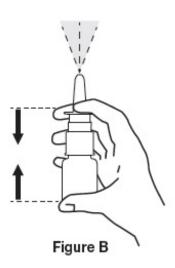


PRIME BOTTLE AGAIN IF NOT USED FOR MORE THAN 2 WEEKS

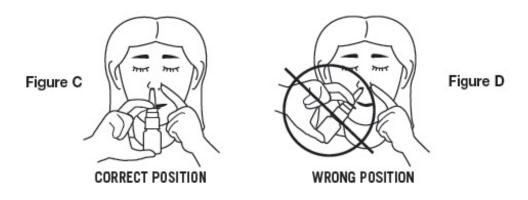
• Repeat steps for priming a bottle (see above).

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).



6. While sniffing gently, spray into nostril.

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

8. A fipe at site pthé 4 n'atalog pg by ', 6 wife nto e zote weit mastissis.ue, 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

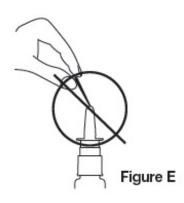
 BEFORE first use, you must get a new bottle ready (primed). If bottle is not used for more than 2 weeks, prime bottle again. 							
Dosing							
ADULTS AND	CHILDREN 12 YEARS OF AGE AND OLDER						
adults and children 12 years of age and older	 once daily, spray 2 times into each nostril while sniffing gently once your allergy symptoms improve, reduce to 1 spray in each nostril per day 						
CHILDF	REN 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 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, 						

Other important information for use				
children under 2 years of age	• do not use			
children 2 to under 6 years of age	 an adult should supervise use once daily, spray 1 time into each nostril while sniffing gently 			
	increase to 2 sprays in each nostril per day. Once allergy symptoms improve, reduce to 1 spray in each nostril per day.			

- 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 you get the spray in your eyes, rinse well with water.
- If allergy symptoms do not improve after one week, stop using and talk to a doctor.
- Do not share this bottle with anyone else as this may spread germs.

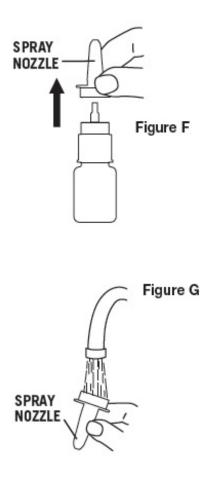
IF PUMP DOES NOT SPRAY PROPERLY, THE NOZZLE MAY BE BLOCKED

- 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.



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 J5

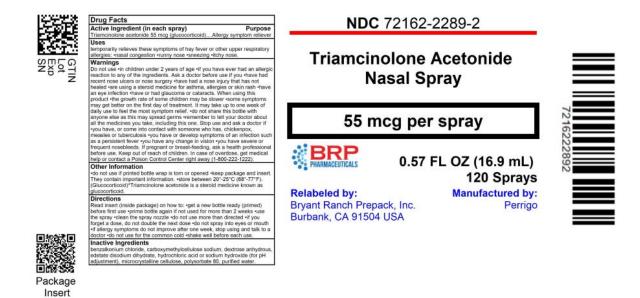
HOW SUPPLIED

Triamcinolone Acetonide Nasal Spray 55 mcg per spray

• NDC 72162-2289-2: 120 Nasal Sprays in a BOTTLE

Repackaged/Relabeled by: Bryant Ranch Prepack, Inc. Burbank, CA 91504

Triamcinolone Acetonide Nasal Spray 55 mcg per spray



Extended Label

ADULTS AND CHILDREN	12 YEARS OF AGE AND OLDER				
adults and children	once daily, spray 2 times into each nostril while sniffing				
12 years of age and	gently				
older	 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 c	hildren may be slower while using this product. Talk to your				
child's doctor if your child r	eeds to use the spray for longer than two months a year.				
 children 6 to under an adult should supervise use 					
12 years of age	 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	 an adult should supervise use 				
years of age	 once daily, spray 1 time into each nostril while sniffing gently 				
children under 2 years of age	• do not use				

TRIAMCINOLONE ACETONIDE NASAL

triamcinolone acetonide spray, metered

Product Information

					Itom Codo		NDC.73163 33		5002 100)
Pı	oduct Type	•	HUMA	N OTC DRUG	item code	(Source)	NDC:72162-22	289(NDC:4	5002-109)
R	oute of Adn	ninistratio	n NASA	L					
A	ctive Ingr	edient/Ac	tive Moie	ty					
			Ingredier	nt Name			Basis of St	trength	Strengt
	NII:F446C597		I DE (UNII: F44	46C597KA) (TR	IAMCINOLONE	ACETONIDE	TRIAMCINOLOI ACETONIDE	NE	55 ug
In	active Ing	gredients							
			Ir	ngredient N	lame			S	strength
BE	NZALKONIU	M CHLORID	e (UNII: F5UM	2KM3W7)					
C A	RBOXYMETH	HYLCELLULC	DSE SODIUM	I, UNSPECIFI	ED (UNII: K679	OBS311)			
	IHYDROUS D								
	ETATE DISO								
			55X04QC321)					
	CDACDVCTA			00102206111	\				
				OP1R32D61U)				
PC W	DLYSORBATE ATER (UNII: 0	80 (UNII: 6C 59QF0KO0R))ZP39ZG8H)	OP1R32D61U)				
PC W/ PI Cc	DLYSORBATE ATER (UNII: 0 roduct Ch plor	80 (UNII: 6C 59QF0KOOR) aracteris)ZP39ZG8H))	Score			
PC W PI Cc Sł	ATER (UNII: 0 roduct Ch plor ape	80 (UNII: 6C 59QF0KOOR) aracteris	DZP39ZG8H) tics)	Size			
PC W/ PI Cc Sh Fla	oLYSORBATE ATER (UNII: 0 roduct Ch blor iape avor	80 (UNII: 6C 59QF0KOOR) aracteris	DZP39ZG8H) tics)		code		
PC W/ PI Cc Sł Flá	ATER (UNII: 0 roduct Ch plor ape	80 (UNII: 6C 59QF0KOOR) aracteris	DZP39ZG8H) tics)	Size	ode		
PC W Cc Sh Fla	oLYSORBATE ATER (UNII: 0 roduct Ch blor iape avor	80 (UNII: 6C 59QF0KOOR) aracteris	DZP39ZG8H) tics			Size	ode		
	olysorbate ater (UNII: 0 roduct Ch olor ape avor ontains	80 (UNII: 6C 59QF0KOOR) aracteris	DZ P39Z G8H) tics WHITE (off wł			Size	ode Marketing Start Date		rketing d Date
PC W PI CC SI FIA CC PA	oLYSORBATE ATER (UNII: 0 roduct Ch olor ape avor ontains ackaging Item	80 (UNII: 6C 59QF0KOOR) aracteris	DZ P39Z G8H) tics WHITE (off wh Packa	hite)		Size Imprint C	Marketing		
PC W C S F I C C C C C C	oLYSORBATE ATER (UNII: 0 roduct Ch olor ape avor ontains ackaging item Code NDC:72162-	80 (UNII: 6C 59QF0KO0R) aracteris 1 in 1 CART 120 in 1 BO	DZ P39Z G8H) tics WHITE (off wh Packa ON	hite) Age Descrip	otion	Size Imprint C	Marketing Start Date		
PC W C S F I C C C C C C	oLYSORBATE ATER (UNII: 0 roduct Ch olor ape avor ontains ackaging item Code NDC:72162-	80 (UNII: 6C 59QF0KO0R) aracteris 1 in 1 CART 120 in 1 BO	DZ P39Z G8H) tics WHITE (off wh Packa ON DTTLE; Type 2	hite) Age Descrip	otion	Size Imprint C	Marketing Start Date		
PC W Sh Fli Cc Pi 4	oLYSORBATE ATER (UNII: 0 roduct Ch olor ape avor ontains ackaging item Code NDC:72162-	80 (UNII: 6C 59QF0KO0R) aracteris 1 in 1 CART 120 in 1 B0 Device/Syst	DZ P39Z G8H) tics WHITE (off wh Packa ON DTLE; Type 2 em (syringe,	hite) Age Descrip	otion	Size Imprint C	Marketing Start Date		
PC W Sh Fli Cc Pi # 1	ATER (UNII: 0 roduct Ch olor ape avor ontains ackaging item Code NDC:72162- 2289-2	80 (UNII: 6C 59QF0KO0R) aracteris 1 in 1 CART 120 in 1 BO Device/Syst g Infori g Ap	DZ P39Z G8H) tics WHITE (off wh Packa ON DTLE; Type 2 em (syringe, mation	hite) Age Descrip	o tion g Delivery	Size Imprint C 03 Marke	Marketing Start Date	En	

Labeler - Bryant Ranch Prepack (171714327)

Registrant - Bryant Ranch Prepack (171714327)

Establishment							
Name	Address	ID/FEI	Business Operations				
Bryant Ranch Prepack		171714327	REPACK(72162-2289), RELABEL(72162-2289)				

Revised: 8/2024

Bryant Ranch Prepack