NASOCLENZ- benzalkonium chloride 0.13% gel Silicon Valley Innovations, Inc.

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

NasoClenz Antiseptic Kit Drug Facts

Active Ingredient

Benzalkonium chloride (0.13%)

Uses

- Helps reduce bacteria that can cause skin infections
- Antiseptic preparation to decrease bacteria on skin

Warnings

For external use only.

Do Not Use

- If you are allegic to any of the ingredients
- In or near eyes
- On children under 2 years of age

Ask a doctor before use if you have

- Deep or puncture wounds
- Serious burns

Stop use and ask a doctor if

- Irritation, swelling, pain or other allergic reaction develops
- Infection occurs

Keep out of reach of children

If swallowed, get medical help or contact a Poison Control Center right away

Directions

- 1. Open gel packets and apply gel to tip of applicator
- 2. Insert tip with gel into the right nostril, rotating it a few times, then rotate it in the

opposite direction.

- 3. Using a second applicator, apply gel to tip and repeat step #2 in the left nostril
- 4. Do not blow nose immediately after use.
- Use every 4-8 hours as needed
- Children under age 12 use adult supervision

Other information

Best if stored at 59-84F (19-29C)

Inactive Ingredients

Carbomer, Diethylene Glycol Monoethyl Ether, Glycerin, Propylene Glycol, Triethanolamine, Water

Questions?

Call 1-844-4MY-NASO (1-844-469-6276) M-F 9am to 5pm PST

Nasoclenz.com

Principal Display Panel



NASOCLENZ benzalkonium chloride 0.13% gel				
Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:81900-013	
Route of Administration	TOPICAL			

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII: 7N6JUD5X6Y)	BENZ ALKONIUM CHLORIDE	1.19 mg in 1 mL	

Inactive Ingredients

Ingredient Name	Strength
DIETHYLENE GLYCOL MONOETHYL ETHER (UNII: A1A118X02B)	126 mg in 1 mL
WATER (UNII: 059QF0K00R)	378 mg in 1 mL
TROLAMINE (UNII: 903K93S3TK)	8.51 mg in 1 mL
CARBOMER HOMOPOLYMER TYPE A (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: F68VH75CJC)	5.67 mg in 1 mL
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	63 mg in 1 mL
GLYCERIN (UNII: PDC6A3C0OX)	677.19 mg in 1 mL

Packaging

#	ltem Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:81900- 013-02	8 in 1 BOX	11/01/2021	
1		1 in 1 POUCH		
1		1 mL in 1 POUCH; Type 1: Convenience Kit of Co- Package		
2	NDC:81900- 013-01	40 in 1 BOX	11/01/2021	
2		1 in 1 POUCH		
2		1 mL in 1 POUCH; Type 1: Convenience Kit of Co- Package		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	11/01/2021	

Labeler - Silicon Valley Innovations, Inc. (118048729)

Registrant - Silicon Valley Innovations, Inc. (118048729)

Establishment				
Name	Address	ID/FEI	Business Operations	
Silicon Valley Innovations, Inc.		118048729	label(81900-013) , pack(81900-013)	