

NUMBIFY SANITIZE- benzalkonium chloride gel

Ridge Properties

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.

Warning: KEEP OUT OF REACH OF CHILDREN. FOR EXTERNAL USE ONLY. NOT FOR USE AROUND THE EYES. IF INGESTED SEEK MEDICAL HELP OR CALL A POISON CONTROL CENTER IMMEDIATELY.

Stop use and ask a doctor if skin becomes irritated, condition worsens, symptoms last longer than 7 days or if symptoms clear up and then return within a few days.

Active Ingredients

Purpose

Benzalkonium Chloride - 0.13%.....	First Aid Antiseptic
Lidocaine HCL - 4%.....	Temporary Relief of Pain & Itching

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Uses: First aid to help prevent bacterial contamination or skin infection, and for temporary relief of pain and itching

Inactive Ingredients: Propylene Glycol, Water, Kava Kava, Acrylates C10-30 Alkyl Acrylate Crosspolymer

Directions: Adults and children 2 years old and over: clean the affected area; spray a small amount on the area 1-3 times daily; may be covered with a sterile bandage (let dry first) * children under 2 years, ask a doctor.

FDA REGISTERED: NDC# 69804-088-12	Do not Use if you have any known allergy to any of the ingredients in this product. Use on, in, or around the eyes Apply over large areas of the body or in large quantities Apply over raw surfaces or blistered areas Discontinue use and seek medical attention should any reaction occur	Numbify Sanitize First Aid Antiseptic & Pain Reliever	Warning: KEEP OUT OF REACH OF CHILDREN. FOR EXTERNAL USE ONLY. NOT FOR USE AROUND THE EYES. IF INGESTED SEEK MEDICAL HELP OR CALL A POISON CONTROL CENTER IMMEDIATELY. Stop use and ask a doctor if skin becomes irritated, condition worsens, symptoms last longer than 7 days or if symptoms clear up and then return within a few days.
Drug Facts: For Professional Use Only Uses: First aid to help prevent bacterial contamination or skin infection, and for temporary relief of pain and itching Inactive Ingredients: Propylene Glycol, Water, Kava Kava, Acrylates C10-30 Alkyl Acrylate Crosspolymer	Directions: Adults and children 2 years old and over: clean the affected area; spray a small amount on the area 1-3 times daily; may be covered with a sterile bandage (let dry first) * children under 2 years, ask a doctor.		Other Information: Product manufactured, packed & distributed by Pain Relief Naturally. In event of a serious adverse reaction please call 1 (877) 906-4806 Or write us at 4995 Ridge DR NE, Salem, OR, 97301 *Avoid Excessive Heat ASK A DR BEFORE USE IF YOU HAVE: Deep or puncture wounds, animal bites, or serious burns
4 Ounce Gel		Active Ingredients Benzalkonium Chloride - 0.13% Lidocaine HCL - 4%	Purpose First Aid Antiseptic Temporary Relief of Pain & Itching

NUMBIFY SANITIZE

benzalkonium chloride gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69804-088
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
LIDOCAINE HYDROCHLORIDE (UNII: V13007Z41A) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE HYDROCHLORIDE ANHYDROUS	400 mg in 10000 mg
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	13 mg in 10000 mg

Inactive Ingredients

Ingredient Name	Strength
PIPER METHYSTICUM ROOT (UNII: BOW48C81XP)	110 mg in 10000 mg
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	6890 mg in 10000 mg
WATER (UNII: 059QF0K00R)	2287 mg in 10000 mg
CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED) (UNII: 59TL3WG5CO)	300 mg in 10000 mg

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69804-088-10	28500 mg in 1 JAR; Type 0: Not a Combination Product	04/29/2020	
2	NDC:69804-088-11	56700 mg in 1 JAR; Type 0: Not a Combination Product	04/29/2020	
3	NDC:69804-088-12	113400 mg in 1 JAR; Type 0: Not a Combination Product	04/29/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	04/29/2020	

Labeler - Ridge Properties (029478762)

Establishment

Name	Address	ID/FEI	Business Operations
Ridge Properties		029478762	manufacture(69804-088)

Revised: 6/2020

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