

EXTRA STRENGTH PRETAT- lidocaine hcl 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.

Directions - *Test skin for sensitivity prior to use & discontinue if sensitivity occurs. Apply thick even layers every 3-5 minutes until desired level of pain relief is reached. Do not use near the eyes.*

Inactive Ingredients: Propylene Glycol, Water, Kava Kava, Copaiba Balsam, Acrylates C10-30 Alkyl Acrylate Crosspolymer, Benzyl Alcohol

Uses - *For temporary relief of tattoo pain*

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

Active Ingredient:

Lidocaine HCL - 4%

Purpose:

Topical Anesthetic

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.

FDA REGISTERED: NDC# 69804-018-12	Do Not Use If you have any known allergy to any of the ingredients in this product. Discontinue use and seek medical attention should any reaction occur	<h1>PRE-TAT</h1> <h2>By TAT BALM</h2> <p>3 in 1 Pre Tattoo Numbing</p> <p>For a Pleasurable Tattoo Experience</p>	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. 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 Purpose: Topical anesthetic Uses: For temporary relief of topical pain
Drug Facts: For Professional Use Only	Directions: Test skin for sensitivity prior to use. Apply thick layers every 3-5 minutes until desired level of pain relief is reached. Discontinue use if sensitivity occurs. Not for use on or near the eyes.		
Active Ingredients: Lidocaine HCL 4%			
Inactive Ingredients: Propylene Glycol, Water, Kava Kava, Copaiba Balsam, Acrylates C10-30 Alkyl Acrylate Crosspolymer, Benzyl Alcohol			
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EXTRA STRENGTH PRETAT			
lidocaine hcl gel			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69804-018
Route of Administration	TOPICAL		
Active Ingredient/Active Moiety			
	Ingredient Name	Basis of Strength	Strength
	LIDOCAINE HYDROCHLORIDE (UNII: V13007Z41A) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE HYDROCHLORIDE ANHYDROUS	40 mg in 1000 mg

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	40 mg in 1000 mg
COPAIBA OIL (UNII: 64VX45Y68N)	180 mg in 1000 mg
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	689 mg in 1000 mg
BENZYL ALCOHOL (UNII: LKG8494WBH)	10 mg in 1000 mg
CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED) (UNII: 59TL3WG5CO)	30 mg in 1000 mg
PIPER METHYSTICUM ROOT (UNII: BOW48C81XP)	11 mg in 1000 mg

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69804-018-10	28350 mg in 1 JAR; Type 0: Not a Combination Product	08/17/2016	
2	NDC:69804-018-11	56699 mg in 1 JAR; Type 0: Not a Combination Product	08/17/2016	
3	NDC:69804-018-12	113398 mg in 1 JAR; Type 0: Not a Combination Product	08/17/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	08/17/2016	

Labeler - Ridge Properties (029478762)

Establishment

Name	Address	ID/FEI	Business Operations
Ridge Properties		029478762	manufacture(69804-018)

Revised: 6/2020

Ridge Properties