EXTRA STRENGTH PRETAT- lidocaine liquid 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.

WARNING - KEEP OUT OF REACH OF CHILDREN, FOR EXTERNAL USE ONLY, NOT FOR USE AROUND THE EYES. IF INGESTED SEEK MEDICAL HELP OR CALL POISON CONTROL IMMEDIATELY.

Uses - For temporary relief of tattoo pain

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

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.



EXTRA STRENGTH PRETAT

lidocaine liquid

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69804-001	
Route of Administration	TOPICAL			

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
LIDO CAINE HYDRO CHLO RIDE (UNII: V13007Z41A) (LIDO CAINE - UNII:98PI200987)	LIDOCAINE HYDROCHLORIDE ANHYDROUS	40 mg in 1000 mg	

Inactive Ingredients		
Ingredient Name	Strength	
PIPER METHYSTICUM ROOT (UNII: BOW48C81XP)	11 mg in 1000 mg	
WATER (UNII: 059QF0KO0R)	69 mg in 1000 mg	

COPAIBA OIL (UNII: 64VX45Y68N)	180 mg in 1000 mg
CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED) (UNII: 59TL3WG5CO)	1 mg in 1000 mg
BENZYL ALCOHOL (UNII: LKG8494WBH)	10 mg in 1000 mg
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	689 mg in 1000 mg

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69804-001- 01	56700 mg in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	11/20/2015	
_	NDC:69804-001- 04	113400 mg in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	09/07/2015	
.5	NDC:69804-001- 07	28500 mg in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	11/30/2015	

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part348	06/08/2015		

Labeler - Ridge Properties (029478762)

Establishment					
Name	Address	ID/FEI	Business Operations		
Ridge Properties		029478762	manufacture (69804-001)		

Revised: 4/2020 Ridge Properties