PRECISION PAIN RELIEF AUDACIOUS WRECK RELIEF- lidocaine hcl 4% liquid Australis Capital (Nevada) 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.

Drug Facts

Active Purpose

Lidocaine HCl 4% Topical Anesthetic

Uses:

For temporary relief of pain and itching due to : sunburn, scrapes, insect bites, minor skin irritations

Warnings

For external use only

Flammable: Do not use while smocking or near heat of flame.

Do not use in large quantities, particularly over raw surfaces and blistered areas.

When using this product

- avoid contact with eyes
- use only as directed
- do not puncture or incinerate
- content under pressure, do not store at temperature above 1200F
- do not store at temperature above 120 ⁰F

Stop use and ask doctor if • condition worsens • redness is present • irritation develops • symptoms persist for more than 7 days or clear up and occur again within a few days

Keep out of reach of children

If accidentally ingested get medical help or contact a Poison Control Center immediately

Direction

- Adults and children 2 years of age and older: apply to affected area not more than 3-4 times daily
- Children under 2 years old: consult a doctor

Inactive ingredients

Acrylates/C10-30 Alkyl Acrylate Crosspolymer Aloe Barbadensis Leaf Extract Aminomethyl Propanol

C30-45 Alkyl Cetearyl Dimethicone Crosspolymer Caprylyl Methicone

Cetearyl Alcohol Ceteth-20 Phosphate Dicetyl Phosphate Dimethicone Disodium EDTA Ethylhexylglycerin

Full Spectrum Hemp Extract

Glyceryl Stearate

Methylparaben

SD Alcohol 40 Steareth-21

Water



PRECISION PAIN RELIEF AUDACIOUS WRECK RELIEF

lidocaine hcl 4% liquid

Pr	od	uct	Into	rma	ation
				عسب	

Product Type HUMAN OTC DRUG Item Code (Source) NDC:82212-002

Route of Administration TOPICAL

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
(LIDOCAINE HYDROCHLORIDE	4 g in 100 mL		

Inactive Ingredients	
Ingredient Name	Strength
CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED) (UNII: 59TL3WG5CO)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)	
CAPRYLYL TRISILOXANE (UNII: Q95M2P1KJL)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
CETETH-20 PHOSPHATE (UNII: 921FTA1500)	
DIHEXADECYL PHOSPHATE (UNII: 2V6E5WN99N)	
DIMETHICONE (UNII: 92RU3N3Y10)	
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
HEMP (UNII: TD1MUT01Q7)	
GLYCERYL MONOSTEARATE (UNII: 2300U9XXE4)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
ALCOHOL (UNII: 3K9958V90M)	
STEARETH-21 (UNII: 53J3F32P58)	
WATER (UNII: 059QF0KO0R)	

ı	Packaging					
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
	1	NDC:82212-002- 02	74 mL in 1 PACKAGE; Type 0: Not a Combination Product	11/05/2021		

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part348	11/05/2021		

Labeler - Australis Capital (Nevada) Inc. (081483723)

Establishment					
Name	Address	ID/FEI	Business Operations		
Inspec Solutions LLC		081030372	manufacture(82212-002)		