PAINLESS TATTOO NUMBING- lidocaine hydrochloride liquid Sambria Pharmaceuticals, LLC

Drug Facts

Active ingredient

Lidocaine HCL 4.0%

Purpose

External Analgesic

Uses

For temporary relief of pain and itching.

Warnings

For external use only.

Flammable: Do not use near heat, flame, or while smoking.

Do not useon wounds or damaged skin, in large quantities, or if you are allergic to any ingredients of this product.

When using this productuse only as directed. Keep away from face to avoid breathing it. Avoid contact with eyes. Do not store at temperatures above 120°F. Do not puncture or incinerate.

Stop use and ask doctor ifcondition worsens, or if symptoms persist for more than 7 days or clear up and occur again within a few days.

Keep out of reach of children and pets If swallowed get medical help or contact a Poison Control Center right away.

Directions

Shake well. Do not spray on face. Adults and children 12 years of age and over: Clean and dry affected area, apply to affected area not more than 3 to 4 times daily. Children 12 years of age or younger: ask a doctor.

Other Information

Protect this product from excessive heat and direct sun.

Inactive Ingredients

Aloe Barbadensis Leaf Extract, Arnica Montana Flower Extract, Aqua (Deionized Water), Dimethyl Sulfone, Disodium EDTA, Ethoxydiglycol, Ethylhexylglycerin, Glycerin, Phenoxyethanol, Propylene Glycol, SD Alcohol 40-B

Product label



PAINLESS TATTOO NUMBING

lidocaine hydrochloride liquid

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:54723-019
Route of Administration	TOPICAL		

Active I	Active Ingredient/Active Moiety		
	Ingredient Name	Basis of Strength	Strength
LIDOCAIN UNII:98PI20	E HYDROCHLORIDE (UNII: V13007Z41A) (LIDOCAINE - 00987)	LIDOCAINE HYDROCHLORIDE	4 g in 100 mL

Inactive Ingredients		
	Ingredient Name	Strength

WATER (UNII: 059QF0KO0R)	
ALCOHOL (UNII: 3K9958V90M)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
DIMETHYL SULFONE (UNII: 9H4PO4Z4FT)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
DIETHYLENE GLYCOL MONOETHYL ETHER (UNII: A1A1I8X02B)	
ARNICA MONTANA FLOWER (UNII: OZ0E5Y15PZ)	
GLYCERIN (UNII: PDC6A3C0OX)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	

l	Packaging				
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
		NDC:54723-019- 01	41 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/09/2024	

Marketing In	larketing Information		
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M017	05/09/2024	

Labeler - Sambria Pharmaceuticals, LLC (078676259)

Revised: 5/2024 Sambria Pharmaceuticals, LLC