PAIN FREE IV- lidocaine cream Sambria Pharmaceuticals, LLC

Drug Facts

Active ingredient

4% Lidocaine

Purpose

External Anesthetic

Uses

For temporary relief of pain and itching due to minor skin irritations.

Warnings

For external use only.

Avoid contact with eyes.

Do not use in large quantities, particularly over raw surface or blistered areas

Stop use and ask doctor if

Condition worsens or if symptons persists more than 7 days or clear up and occur again within a few days. Discontinue use.

Keep out of reach of children

If swallowed, get medical help or contact a Poison Control Center right away.

Directions

For adults and children two-years or older: Apply to affected area not more than 3 or 4 times daily. Children under 2 years of age: consult a physician.

Inactive ingredients

Aqua (Deionized Water), Arnica Montana Floweri Extract, C13-14 Isoparaffin, Chondroitin Sulfate, Emu Oil, Ethoxydiglycol, Ethylhexylglycerin, Glucosamine Sulfate, Isopropyl Palmitate, Laureth-7, Melaleuca Alternifolia (Tea Tree) Oil, Methylsulfonylmenthane (MSM), Phenoxyethanol, Polyacrylamide, Propylene Glycol, Stearic Acid, Triethanolamine.

Other information

Protect this product from excessive heat and direct sun.

Question or Comments

FDA Registered : rico@painfree-iv.com

Other information



PAIN FREE IV

lidocaine cream

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Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:54723-008
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
LIDOCAINE (UNII: 98PI200987) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE	4 g in 100 mL

Inactive Ingredients		
Ingredient Name	Strength	
WATER (UNII: 059QF0KO0R)		
ARNICA MONTANA FLOWER (UNII: OZ0E5Y15PZ)		
C13-14 ISOPARAFFIN (UNII: E4F12ROE70)		
ELOSULFASE ALFA (UNII: ODJ69JZG85)		
EMU OIL (UNII: 344821WD61)		
DIETHYLENE GLYCOL MONOETHYL ETHER (UNII: A1A1I8X02B)		
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)		
GLUCOSAMINE SULFATE (UNII: 1FW7WLR731)		
ISOPROPYL PALMITATE (UNII: 8CRQ2TH63M)		
LAURETH-7 (UNII: Z95S6G8201)		
TEA TREE OIL (UNII: VIF565UC2G)		
DIMETHYL SULFONE (UNII: 9H4PO4Z4FT)		
PHENOXYETHANOL (UNII: HIE492ZZ3T)		
POLYACRYLAMIDE (10000 MW) (UNII: E2KR9C9V2I)		
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)		
STEARIC ACID (UNII: 4ELV7Z65AP)		
TROLAMINE (UNII: 903K93S3TK)		

l	P	Packaging				
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
	1		4 mL in 1 PACKET; Type 0: Not a Combination Product	07/20/2022		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M017	07/20/2022	

Labeler - Sambria Pharmaceuticals, LLC (078676259)