

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 symptoms 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

0.25" SEAL AREA

123456789

0.25"

Drug Facts

Active Ingredients	Purpose
Lidocaine 4.0%	External Analgesic

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

Warnings
For external use only
Avoid contact with eyes
Do not use in large quantities, particularly over raw surfaces or blistered areas
Stop use and ask doctor if
• Condition worsens, or if symptoms persist for more than 7 days or clear up and occur again within a few days. Discontinue use.
Keep out of reach of children
• If product is 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 to 4 times daily. Children under 2 years of age: consult a physician. Apply in a circular motion for 30 to 60 seconds.

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

Other Information
Protect this product from excessive heat and direct sun.

Questions or Comments?
FDA Registered:
rico@painfree-iv.com

Distributed by PainFree-iv Corp
20200 west Dixie Hwy Suite #902 Aventura, Florida 33180
Made in the USA

SEAL AREA 0.25"

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PAIN FREE IV

lidocaine cream

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: A1A18X02B)	
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: 9O3K93S3TK)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54723-008-01	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)