

FRANKLYNUMB 2- lidocaine cream
Sambria Pharmaceuticals, LLC

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 ingredient

Lidocaine 4%

Purpose

External Analgesic

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 the raw surfaces or blistered area

Stop use and ask a doctor if

condition worsens, or if symptoms persists for more than 7 days or clear up and occur again within the 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 or 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), Arnica Montana Flower Extract, C13-14 Isoparaffin, Chondroitin Sulfate, Emu Oil, Ethoxydiglycol, Ethylhexylglycerin, Glucosamine Sulfate, Isopropyl Palmitate, Laureth-7, Melaleuca Alternifolia (Tea Tree) Oil, Methylsulfonylmethane (MSM), Phenoxyethanol, Polyacrylamide, Propylene Glycol, Stearic Acid, Triethanolamine.

Other information

Protect this product from excessive heat and direct sun.

Questions or comments?

support@franklynumb.com

Product label

Drug Facts		 
Active Ingredients	Purpose	
Lidocaine 4.0%	External Analgesic	
Uses		
For temporary relief of pain and itching due to minor skin irritation.		
Warnings		
<p>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</p> <ul style="list-style-type: none"> • Condition worsens, or if symptoms persist for more than 7 days or clear up and occur again within a few days. Discontinue use. <p>Keep out of reach of children</p> <ul style="list-style-type: none"> • If product is swallowed, get medical help or contact a Poison Control Center right away. 		
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Other Information		
Protect this product from excessive heat and direct sun.		
Questions or Comments?		
support@franklynumb.com		
<p>Manufactured for FranklyNumb™ Made in the USA</p>		 <p>(Step 2 with Lidocaine) 4ml/.13 fl.oz</p>

FRANKLYNUMB 2

lidocaine cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:54723-002
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)	
CHONDROITIN SULFATE (BOVINE) (UNII: 6IC1M3OG5Z)	
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: 9O3K93S3TK)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54723-002-01	4 mL in 1 POUCH; Type 0: Not a Combination Product	12/08/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	12/08/2021	

