SCALPANUMB- 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% w/w

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.

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.

Keep out of reach of children

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

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.

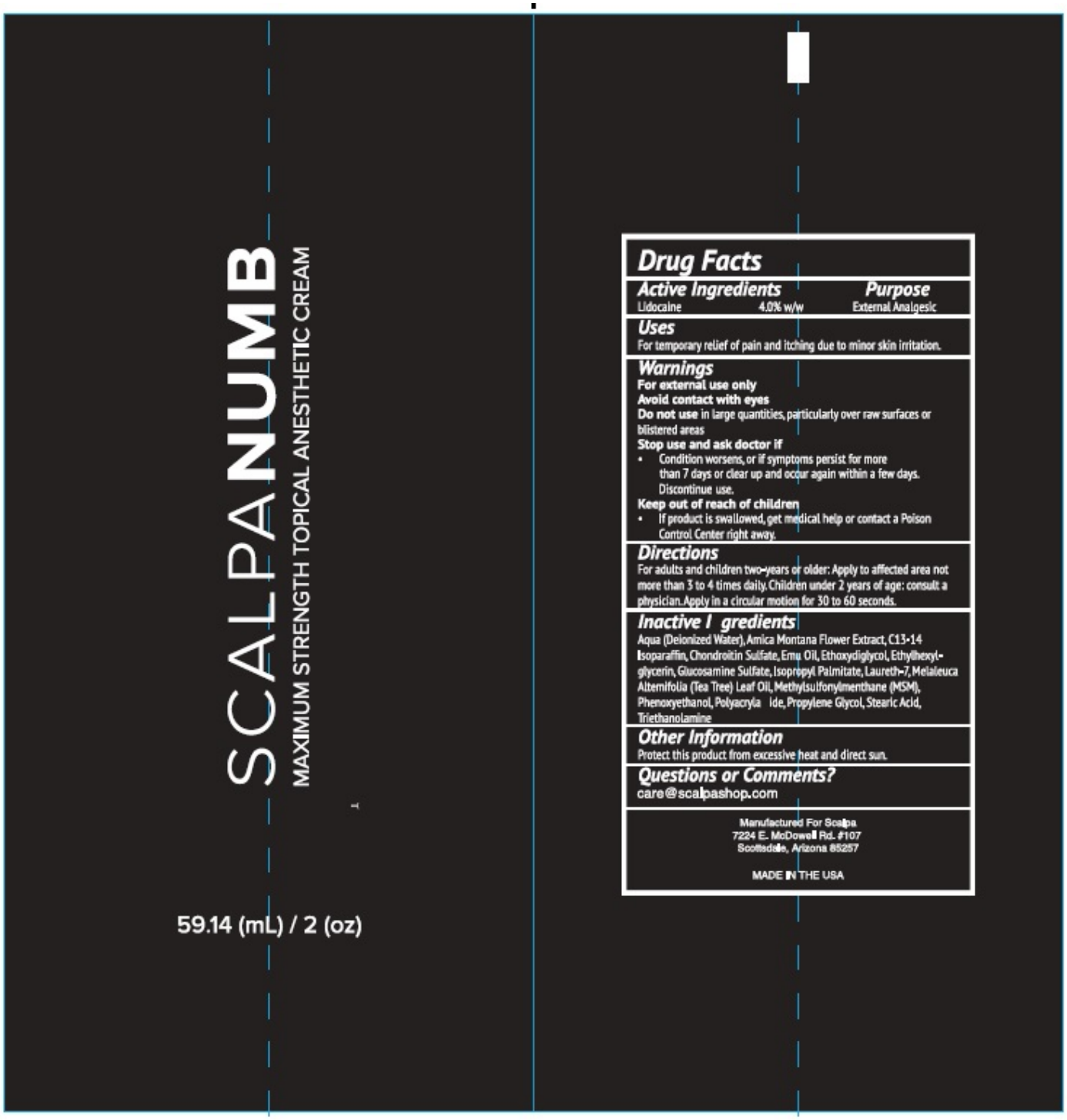
Other information

Protect this product from excessive heat and direct sun.

Questions or comments?

care@scalpashop.com

Product label



SCALPANUMB

lidocaine cream

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:54723-001
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)	
SODIUM CHONDROITIN SULFATE (PORCINE; 5500 MW) (UNII: H5BJH23Z9A)	
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)	
MELALEUCA ALTERNIFOLIA LEAF (UNII: G43C57162K)	
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:54723-001-01	59.14 mL in 1 TUBE; Type 0: Not a Combination Product	09/16/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	09/16/2021	

Labeler - Sambria Pharmaceuticals, LLC (078676259)

Establishment

Name	Address	ID/FEI	Business Operations
Speciality Pharma Manufacturing, LLC		013957125	manufacture(54723-001)

Revised: 9/2021 Sambria Pharmaceuticals, LLC