

ECLIPSE TOPICAL ANALGESIC LL- tetracaine hcl cream
Sambria Pharmaceuticals, Inc.

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.

Eclipse LL Topical Analgesic

☐Active Ingredients

Tetracaine HCL 2.0% w/w

☐Purpose

External Analgesic

☐Uses

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

☐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 a 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), Arnica Montana Flower Extract, C13-14 Isoparaffin, Chondroitin Sulfate, Emu Oil, Ethoxydiglycol, Ethylhexylglycerin, Glucosamine Sulfate, Isopropyl Palmitate, Laureth-7, Melaleuca Alternifolia (Tea Tree) Leaf Oil, Methylsulfonylmethane (MSM), Phenoxyethanol, Polyacrylamide, Propylene Glycol, Stearic Acid, Triethanolamine

☐Other Information

Protect this product from excessive heat and direct sun.

☐Questions or Comments?

FDA Registered: NDC No. 54723-669-05

800-759-6876

ECLIPSE LL
 TOPICAL ANALGESIC

2% Tetracaine Long-lasting
 Topical Analgesic

T
TETRACAINE

5 mL / .169 fl. oz.

Distributed by Eclipse Anesthetics, LLC
 5915 South Creek Dr., #110
 The Colony, TX 75066
 and Shreveport, Louisiana, LA
 70175
 Made in the USA

Drug Facts
 Purpose: Topical Analgesic
 Active Ingredients: 2% w/w Tetracaine HCl
 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 and do not use over wide areas or for extended periods.
 Stop use and ask doctor if:
 - Rash or severe itching occurs.
 - Symptoms persist for more than 7 days or come up and come again within 14 days.
 Keep out of reach of children.
 - If product is swallowed, get medical help or contact a Poison Control Center right away.
 Directions: Rub into and rub gently. Rub gently in circles. Rub into skin 3 to 4 times daily. Children under 2 years of age consult a physician. Apply to smaller areas for 10 to 15 seconds.
 Inactive Ingredients: Aqua, Glycerine, Methyl Methacrylate, Triethyl Citrate, Ethylhexyl Stearate, Dimethylsiloxane, Benzyl Alcohol, Carbomer, Dimethylammonium Chloride, Methylparaben, Propylparaben, Potassium Hydroxide, Sorbic Acid, Triphenylethylmethane Sulfonate.
 Other information: Protect this product from moisture heat and light.
 Questions or Comments? Call 1-800-445-1145.

ECLIPSE TOPICAL ANALGESIC LL
 tetracaine hcl cream

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:54723-669
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TETRACAINE HYDRO CHLORIDE (UNII: 5NF5D4OPCI) (TETRACAINE - UNII:0619F35CGV)	TETRACAINE HYDROCHLORIDE	20 mg in 1000 mg

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
ARNICA MONTANA FLOWER (UNII: OZ0E5Y15PZ)	
C13-14 ISOPARAFFIN (UNII: E4F12ROE70)	
CHONDRO ITIN SULFATE SODIUM (BOVINE) (UNII: 8QTV3DTT8W)	
EMU OIL (UNII: 344821WD61)	
DIETHYLENE GLYCOL MONOETHYL ETHER (UNII: A1A118X02B)	
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)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TROLAMINE (UNII: 9O3K93S3TK)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54723-669-05	5 mg in 1 PACKET; Type 0: Not a Combination Product	05/01/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	05/01/2017	

Labeler - Sambria Pharmaceuticals, Inc. (078676259)**Establishment**

Name	Address	ID/FEI	Business Operations
A.I.G. Technologies, Inc.		171837367	manufacture(54723-669)

Establishment

Name	Address	ID/FEI	Business Operations
JP Packaging LLC		151369456	repack(54723-669)