ECLIPSE TOPICAL ANESTHETIC- lidocaine hydrochloride cream
Sambria Pharmaceuticals

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 Topical Anesthetic

Active Ingredient

Lidocaine HCL 4.00% w/w

Purpose

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 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 or 4 times daily. Children under 2 years of age: consult a physician. Apply in a circular motion for 50 to 60 seconds.

Inactive Ingredients

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

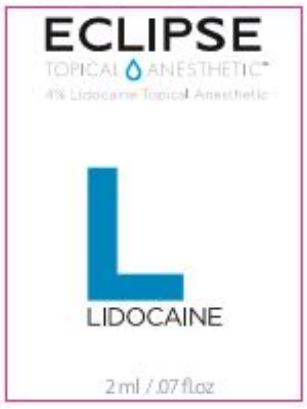
Other Information

Protect this product from excessive heat and direct sun.

Questions or Comments?

FDA Registered: NDC No. 54723-667-10

800-759-6876



ECLIPSE TOPICAL ANESTHETIC

lidocaine hydrochloride cream

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:54723-667
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
LIDOCAINE HYDROCHLORIDE (UNII: V13007Z41A) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE HYDROCHLORIDE ANHYDROUS	40 mg in 1 g

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:54723-667-10	2 g in 1 PACKET; Type 0: Not a Combination Product	02/01/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	08/20/2015	

Labeler - Sambria Pharmaceuticals (078676259)

Establishment

Name	Address	ID/FEI	Business Operations
A.I.G. Technologies, Inc.		171837367	manufacture(54723-667)

Establishment

Name	Address	ID/FEI	Business Operations
JP Packaging LLC		151369456	repack(54723-667)

Revised: 8/2018 Sambria Pharmaceuticals