**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.*

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**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 30 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. 54723-667-05

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:54723-667-05 | 0.005 g in 1 PACKET; Type 0: Not a Combination Product | 05/03/2017 | |

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---|---|---|---|
| OTC monograph not final | part348 | 05/03/2017 | |

## 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) |