

COMFORTOX LIDOCAINE- 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.

Comfortox L

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, Chondroitin 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.

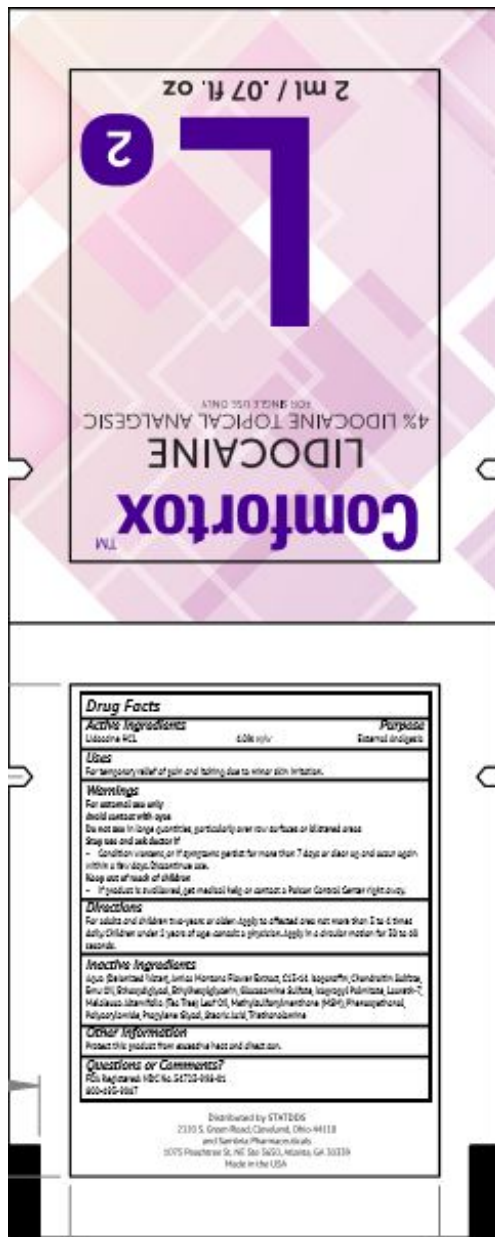
☐ ***Other Information***

Protect this product from excessive heat and direct sun.

☐ ***Questions or Comments?***

FDA Registered: NDC No. 54723-998-01

800-693-9067



COMFORTOX LIDOCAINE

lidocaine hydrochloride cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:54723-998
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 1000 mg

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: A1A118 X02B)	
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:54723-998-01	2000 mg in 1 PACKET; Type 0: Not a Combination Product	09/14/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	09/14/2016	

Labeler - Sambria Pharmaceuticals (078676259)**Establishment**

Name	Address	ID/FEI	Business Operations
A.I.G. Technologies, Inc.		171837367	manufacture(54723-998)

Establishment

Name	Address	ID/FEI	Business Operations
JP Packaging LLC		151369456	repack(54723-998)