COMFORTOX TETRACAINE- 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.

Comfortox T

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 then 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.

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. 54723-997-01

800-693-9067

COMFORTOX TETRACAINE

tetracaine hcl cream

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:54723-997
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TETRACAINE HYDROCHLORIDE (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)	
CHONDROITIN SULFATE SODIUM (BOVINE) (UNII: 8QTV3DTT8W)	
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)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TROLAMINE (UNII: 9O3K93S3TK)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54723-997-01	1500 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, Inc. (078676259)

Establishment

Name	Address	ID/FEI	Business Operations
A.I.G. Technologies, Inc.		086365223	manufacture(54723-997)

Establishment

Name	Address	ID/FEI	Business Operations
JP Packaging LLC		151369456	repack(54723-997)