COMFORTOX BENZOCAINE- benzocaine cream
Sambria Pharmaceuticals, Inc.

Comfortox B

Active Ingredients

Benzocaine 20.0% 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

Stop use and ask 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 then 3 or 4 times daily. Children under 2 years of age: consult a physician.

Inactive Ingredients

Aqua (Deionized Water), Arnica Montana Flower Extract, C13-14 Isoparaffin, Caprylic/Capric Triglyceride, Ceteareth-25, Chondroitin Sulfate, Diethylhexyl Sodium Sulfosuccinate, Emu Oil, Ethoxydiglycol, Ethylhexylglycerin, Glucosamine Sulfate, Glycerin, Isopropyl Palmitate, Laureth-7, Melaleuca alternifolia (Tea Tree) Leaf Oil, Methylfulfonylmenthane (MSM), Phenoxyethanol, Polyacrylamide, Polysorbate-20, Safflower Oil, Stearic Acid, Triethanolamine

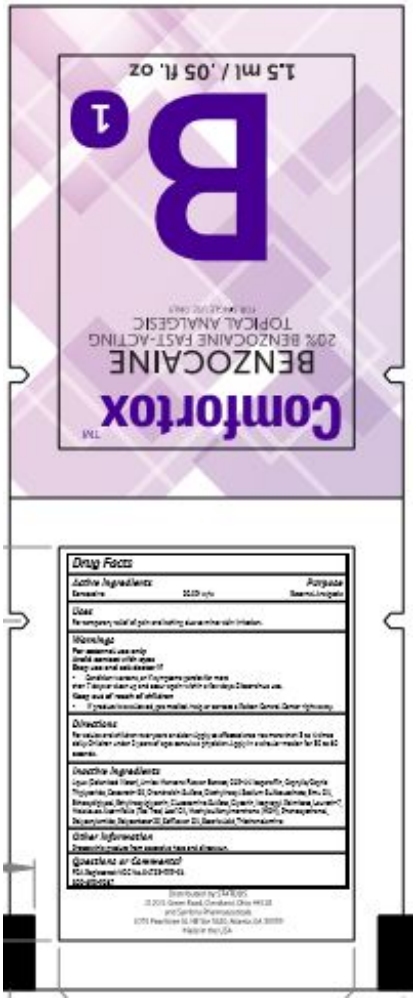
Other Information

Protect this product from excessive heat or direct sun.

Questions or Comments?

FDA Registered: NDC No. 54723-999-01

800-693-9067



COMFORTOX BENZOCAINE

benzocaine cream

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:54723-999
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
BENZOCAINE (UNII: U3RSY48JW5) (BENZOCAINE - UNII:U3RSY48JW5)	BENZOCAINE	20 mg in 100 mg

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
ARNICA MONTANA FLOWER (UNII: OZ0E5Y15PZ)	
C13-14 ISOPARAFFIN (UNII: E4F12ROE70)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
CETEARETH-25 (UNII: 8FA93U5T67)	
CHONDROITIN SULFATE SODIUM (BOVINE) (UNII: 8QTV3DTT8W)	
DOCUSATE SODIUM (UNII: F05Q2T2JA0)	
EMU OIL (UNII: 344821WD61)	
DIETHYLENE GLYCOL MONOETHYL ETHER (UNII: A1A1I8X02B)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
GLUCOSAMINE SULFATE (UNII: 1FW7WLR731)	
GLYCERIN (UNII: PDC6A3C0OX)	
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)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
SAFFLOWER OIL (UNII: 65UEH262IS)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TROLAMINE (UNII: 9O3K93S3TK)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54723-999-01	1500 mg in 1 PACKET; Type 0: Not a Combination Product	09/07/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M017	09/07/2016	

Labeler - Sambria Pharmaceuticals, Inc. (078676259)

Establishment

Name	Address	ID/FEI	Business Operations
A.I.G. Technologies, Inc.		086365223	manufacture(54723-999)

Revised: 11/2023 Sambria Pharmaceuticals, Inc.