

ECLIPSE TOPICAL ANALGESIC FA- benzocaine 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.

Eclipse FA Topical Analgesic

☐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 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.

☐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. 54723-667-08

800-759-6876



ECLIPSE TOPICAL ANALGESIC FA			
benzocaine cream			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:54723-668
Route of Administration	TOPICAL		
Active Ingredient/Active Moiety			
Ingredient Name		Basis of Strength	Strength
BENZO CAINE (UNII: U3RS Y48JW5) (BENZO CAINE - UNII:U3RS Y48JW5)		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)			
CHONDRO ITIN SULFATE SODIUM (BO VINE) (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:54723-668-08	1500 mg 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	02/01/2016	

Labeler - Sambria Pharmaceuticals, Inc. (078676259)

Establishment

Name	Address	ID/FEI	Business Operations
A.I.G. Technologies, Inc.		171837367	manufacture(54723-668)

Establishment

Name	Address	ID/FEI	Business Operations
JP Packaging LLC		151369456	repack(54723-668)

Revised: 8/2018

Sambria Pharmaceuticals, Inc.