

NEUROMED FA- benzocaine cream
Sambria Pharmaceuticals, Inc.

NeuroMed 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, Cetaretj-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. 54723-668-03

800-759-6876

Product label

B¹
BENZOCAINE

NEUROMED^{FA}

20% BENZOCAINE FAST-ACTING
TOPICAL ANESTHETIC

5 ml / .169 fl.oz

Drug Facts	Active Ingredients Benzocaine 20.0% w/v Editorial Review
Uses	For temporary relief of pain and itching due to minor skin irritations.
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. - 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. Apply to a circular area for 10 to 60 seconds.
Inactive Ingredients	Agua (Purified Water), Arnia Natural Flower Extract (C1)-14, Isoeugenol, Caprylic/Capric Triglyceride, Cinnamyl-25, Cholesterol, Salicin, Butylphenyl Methyl Sulfonamide, Ethyl Oleoylethylglycolate, Ethylhexylglycerol, Glyceryl Stearate, Glyceryl Palmitate, Lauric-1-Methyl Hexan-3-yl (The The) Laur DL-Methylbutylmethylamine, 2-(2-Ethoxyethyl) Hexanoate, Polysorbate-20, Sorbitol, DL-Sorbitol, and Tetrahydrofuran.
Other Information	Please see this product first on active ingredient list and then see questions or comments.
Questions or Comments?	800-244-6601 Manufactured for Samba Pharmaceuticals 1075 Peachtree St. NE, Ste 5010, Atlanta, GA 30319 Made in the USA.



NEUROMED FA

benzocaine cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:54723-722
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: 8QTV3D TT8W)
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:54723-722-05	5000 mg in 1 PACKET; Type 0: Not a Combination Product	08/21/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M017	08/21/2017	

Labeler - Sambria Pharmaceuticals, Inc. (078676259)

Establishment

Name	Address	ID/FEI	Business Operations
A.I.G. Technologies, Inc.		086365223	manufacture(54723-722)

Revised: 11/2023

Sambria Pharmaceuticals, Inc.