

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

NEUROMEDTM FA
20% BENZOCAINE TOPICAL ANALGESIC
3 ml / .10 fl.oz

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Drug Facts

| Active Ingredients | Purpose |
|----------------------|--------------------|
| Benzocaine 20.0% w/w | External Analgesic |

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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 5 to 4 times daily. Children under 2 years of age: consult a physician. Apply in a circular motion for 30 to 60 seconds.

Inactive Ingredients
Aqua (Deionized Water), Arisa Montana Flower Extract, C13-14 Isoparaffin, Ethylhexyl Stearic Thioacetate, Glycerin-15, Cholesterol Sulfate, Diethylhexyl Sodium Sulfosuccinate, Erucyl Ethanol Glycol, Ethylhexylglycerin, Glycerin Sulfate, Glycerin, Isopropyl Palmitate, Laureth-7, Melaleuca Alternifolia (Tea Tree) Leaf Oil, Methylparaben, Methylparaben (MSM), Phenacetin, Polystyrene, Polysorbate-20, Safflower Oil, Stearic Acid, Triethanolamine

Other Information
Protect this product from excessive heat and direct sun.

Questions or Comments?
FDA Registered: NDC No. 54723-668-03
800-759-6876

Manufactured for Samba Pharmaceuticals
1075 Peachtree St. NE Ste 3650, Atlanta, GA 30339
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: 8QTV3DTT8W) |
| DOCUSATE SODIUM (UNII: F05Q2T2JA0) |
| EMU OIL (UNII: 344821WD61) |
| DIETHYLENE GLYCOL MONOETHYL ETHER (UNII: A1A18X02B) |
| 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:54723-722-03 | 3000 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 Drug | M017 | 02/01/2016 | |

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.