

PAINLESS TATTOO 3- tetracaine cream
Sambria Pharmaceuticals, LLC

Drug Facts

Active ingredient

Tetracaine 2%

Purpose

External Analgesic

Uses

For temporary relief of pain and itching due to minor skin irritation.

Warnings

For external use only.

Do not use onwounds or damaged skin, in large quantities, or if you are allergic to any ingredients of this product.

When using this productuse only as directed. Avoid contact with the eyes, rashes, or mucous membranes.

Stop use and ask doctor ifcondition worsens, or if symptoms persist for more than 7 days or clear up and occur again within a few days.

Keep out of reach of children and petsIf swallowed get medical help or contact a Poison Control Center right away.

Directions

Adults and children 12 years of age and over:

Clean and dry affected area, apply to affected area not more than 3 to 4 times daily.

Children 12 years of age or younger: ask a doctor.

Other Information

Protect this product from excessive heat and direct sun.

Inactive Ingredient

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

Product label



Drug Facts

Active Ingredients	Purpose
Tetracaine 2.0%	External Analgesic

Uses
For temporary relief of pain and itching.

Warnings
For external use only.
Do not use on wounds or damaged skin, in large quantities, or if you are allergic to any ingredients of this product.
When using this product use only as directed. Avoid contact with the eyes, rashes, or mucous membranes.
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.
Keep out of reach of children and pets
If swallowed get medical help or contact a Poison Control Center right away.

Directions
Adults and children 12 years of age and over:
Clean and dry affected area, apply to affected area not more than 3 to 4 times daily. **Children 12 years of age or younger:** ask a doctor.

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

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



Made In The USA

• **Directions** •



PAINLESS TATTOO 3

tetracaine cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:54723-017
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name		Basis of Strength	Strength	
TETRACAINE (UNII: 0619F35CGV) (TETRACAINE - UNII:0619F35CGV)		TETRACAINE	2 g in 100 mL	
Inactive Ingredients				
Ingredient Name			Strength	
WATER (UNII: 059QF0KO0R)				
ARNICA MONTANA FLOWER (UNII: OZ0E5Y15PZ)				
C13-14 ISOPARAFFIN (UNII: E4F12ROE70)				
CHONDROITIN SULFATE (BOVINE) (UNII: 6IC1M3OG5Z)				
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)				
TEA TREE OIL (UNII: VIF565UC2G)				
DIMETHYL SULFONE (UNII: 9H4PO4Z4FT)				
PHENOXYETHANOL (UNII: HIE492ZZ3T)				
POLYACRYLAMIDE (CROSSLINKED; 2 MOLE PERCENT BISACRYLAMIDE) (UNII: 9FPL31B58Q)				
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)				
STEARIC ACID (UNII: 4ELV7Z65AP)				
TROLAMINE (UNII: 9O3K93S3TK)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54723-017-01	3 mL in 1 PACKET; Type 0: Not a Combination Product	09/26/2023	
Marketing Information				
Marketing Category		Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug		M017	09/26/2023	

Labeler - Sambria Pharmaceuticals, LLC (078676259)

Establishment

Name	Address	ID/FEI	Business Operations
Southeast Holdings Corp		080504027	manufacture(54723-017)