INDERMA MD- tetracaine cream
Sambria Pharmaceuticals, LLC

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.

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
Avoid contact with eyes
Do not use in large quantities, particularly over raw surfaces or blistered areas

Stop use and ask a doctor if

Condition worsens or, if symptoms persists for more than 7 days or clear up and occur again within a few days. Discontinue use

Keep out of reach of children

If 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. Apply in a circular motion for 30 to 60 seconds.

Inactive ingredients

Aqua (Deionized Water), Arnica Montana Flower Extract, C13-14 Isoparaffin,

Chrondroitin Sulfate,
Emu Oil, Ethoxydiglycol, Ethylhexyglycerin, Glucosamine Sulfate, Isopropyl Palmitate, Laureth-7, Melaleuca Alternifolia (Tea Tree) Oil, Methylsulfonylmethane (MSM), Phenoxyethanol, Polyacrylamide, Propylene Glycol, Stearic Acid, Triethanolamine.

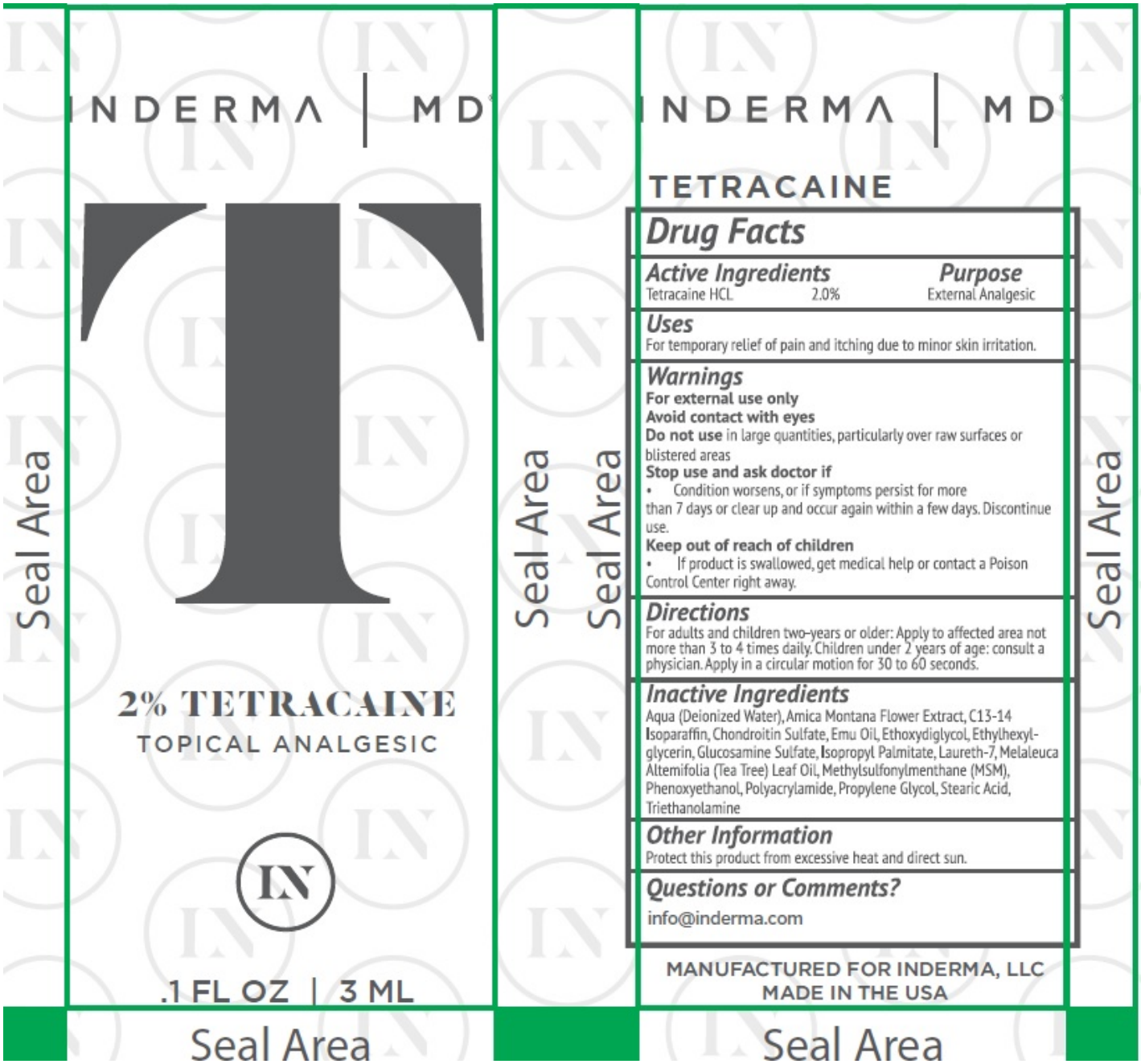
Other information

Protect this product from excessive heat and direct sun.

Questions and Comments?

info@inderma.com

Product label



INDERMA MD

tetracaine cream

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:54723-011
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)	
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)	
ELOSULFASE ALFA (UNII: ODJ69JZG85)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:54723-011-01	3 mL in 1 PACKET; Type 0: Not a Combination Product	03/31/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	03/31/2023	

Labeler - Sambria Pharmaceuticals, LLC (078676259)

Revised: 4/2023 Sambria Pharmaceuticals, LLC