INDERMA MD- benzocaine 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

Benzocaine 20%

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 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 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

benzocaine cream

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:54723-009
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZOCAINE (UNII: U3RSY48JW5) (BENZOCAINE - UNII:U3RSY48JW5)	BENZOCAINE	20 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:54723-009-01	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