

ULTRA PAIN-A-TRATE PAIN-RELIEVING CREAM- camphor and menthol and methyl salicylate cream
Melaleuca, Inc.

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.

Ultra Pain-A-Trate Pain-Relieving Cream

Active ingredients

Camphor 4%

Menthol 10%

Methyl Salicylate 30%

Purpose

Topical analgesic

Indications For the temporary relief of minor aches and pains of muscles and joints associated with simple backache, arthritis, strains, bruises, and sprains. Provides penetrating relief.

Warnings

For external use only

Do not use

- on wounds or damaged skin
- with a heating pad
- on a child under 12 years of age with arthritis-like conditions

Ask a doctor before use if you have redness over the affected area.

When using this product

- avoid contact with eyes or mucus membranes
- do not bandage tightly

Stop use and ask a doctor if

- condition worsens or symptoms persist for more than 7 days
- symptoms clear up and occur again within a few days
- excessive skin irritation occurs

Keep out of reach of children to avoid accidental ingestion. If swallowed, get medical help or contact a Poison Control Center right away.

Directions


- apply to affected area with gentle massage
- do not apply more than 3 to 4 times daily

Other information do not store above 95°F (35°C)

Inactive ingredients acrylates/C10-30 alkyl acrylate crosspolymer, benzyl alcohol, deionized water, glyceryl monostearate SE, melaleuca alternifolia (tea tree) leaf oil, polysorbate 80, propanediol, steareth-2, steareth-21, stearic acid, triethanolamine

Diameter x Length = 1-3/8" x 5-1/2"

4-1/4"



Drug Facts

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OPEN END

1/4"

3/16"

PRINT HEIGHT Per Artwork

TUBE LENGTH 5-1/2"

CAP END

Melaleuca, Inc.
Idaho Falls, ID 83402
1-800-282-3000 • Melaleuca.com
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NOT FOR RESALE

ULTRA PAIN-A-TRATE PAIN-RELIEVING CREAM

camphor and menthol and methyl salicylate cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:54473-334
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CAMPHOR (SYNTHETIC) (UNII: 5TJD82A1ET) (CAMPHOR (SYNTHETIC) - UNII:5TJD82A1ET)	CAMPHOR (SYNTHETIC)	3.4 g in 85 g
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	8.5 g in 85 g
METHYL SALICYLATE (UNII: LAV5U5022Y) (SALICYLIC ACID - UNII:O414PZ4LPZ)	METHYL SALICYLATE	25.5 g in 85 g

Inactive Ingredients

Ingredient Name	Strength
TROLAMINE (UNII: 9O3K93S3TK)	
PROPANEDIOL (UNII: 5965N8W85T)	
STEARETH-2 (UNII: V56DFE46J5)	
CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED) (UNII: 59TL3WG5CO)	
WATER (UNII: 059QF0KO0R)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TEA TREE OIL (UNII: VIF565UC2G)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
GLYCERYL STEARATE SE (UNII: FCZ5MH785I)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
STEARETH-21 (UNII: 53J3F32P58)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54473-334-03	85 g in 1 TUBE; Type 0: Not a Combination Product	10/01/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	10/01/2021	

Labeler - Melaleuca, Inc. (139760102)

Establishment

Name	Address	ID/FEI	Business Operations
Melaleuca, Inc		079711683	manufacture(54473-334)

Revised: 1/2023

Melaleuca, Inc.