# ORIGINAL 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.

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### Original Pain-A-Trate Pain-Relieving Cream

### Active ingredients

Camphor 3.25%

Menthol, 1.5%

Methyl Salicylate, 15%

### **Purpose**

Topical analgesic

**Indications** For the temporary relief of minor aches and pains of muscles and joints associated with simple backache, arthritis, strains, bruises, sprains. Provides penetrating pain 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, aloe barbadensis flower extract, benzyl alcohol, cetyl alcohol, chlorophyllin-copper complex, coccinia indica fruit extract, corallina officianalis extract, curcuma longa (turmeric) root extract, ethylhexylglyverin, glyceryl monostearate SE, melaleuca alternifolia (tea tree) leaf oil, melia azadirachta flower extract, melia azadirachta leaf extract, ocimum basilicum (basil) flower/leaf extract, ocimum sanctum (holy basil) leaf extract, polysorbate 20, solanum melongena (eggplant) fruit extract, sorbitan stearate, stearic acid, triethanolamine, water



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Melaleuca, Inc.
Idaho Falls, ID 83402
208-534-3000 • Melaleuca,com
Made in the USA with thoughtfully
selected globally sourced ingredients
N° 184 08/22 U
NOT FOR RESALE



### ORIGINAL PAIN-A-TRATE PAIN-RELIEVING CREAM

camphor and menthol and methyl salicylate cream

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:54473-335
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
CAMPHOR (SYNTHETIC) (UNII: 5TJD82A1ET) (CAMPHOR (SYNTHETIC) - UNII:5TJD82A1ET)	CAMPHOR (SYNTHETIC)	32.5 mg in 1 g	
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	15 mg in 1 g	
METHYL SALICYLATE (UNII: LAV5U5022Y) (SALICYLIC ACID - UNII:0414PZ4LPZ)	METHYL SALICYLATE	150 mg in 1 g	

Inactive Ingredients	
Ingredient Name	Strength
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
AZADIRACHTA INDICA FLOWER (UNII: 3TE8A92UPM)	
GLYCERYL STEARATE SE (UNII: FCZ5MH785I)	
WATER (UNII: 059QF0KO0R)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
SORBITAN MONOSTEARATE (UNII: NVZ 410H58X)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
TEA TREE OIL (UNII: VIF565UC2G)	
COCCINIA GRANDIS FRUIT (UNII: VLJ6WOT3K5)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
CORALLINA OFFICINALIS (UNII: 4004498D06)	
CURCUMA LONGA WHOLE (UNII: W5488JUO8U)	
OCIMUM BASILICUM FLOWERING TOP (UNII: 7SAB275FP2)	
OCIMUM GRATISSIMUM LEAF OIL (UNII: AVG2506KDV)	
TROLAMINE (UNII: 903K93S3TK)	
SODIUM COPPER CHLOROPHYLLIN A (UNII: VAC44EX123)	
AZADIRACHTA INDICA LEAF (UNII: HKY915780T)	
SOLANUM MELONGENA WHOLE (UNII: 5DS5EE0N93)	
ALOE VERA FLOWER (UNII: 575DY8C1ER)	
CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED) (UNII: 59TL3WG5CO)	

Product Characteristics			
Color	Score		
Shape	Size		
Flavor	Imprint Code		
Contains			

Packaging			
# Itom Codo	Packago Doccrintion	Marketing Start	Marketing End

# Item Code	Раскаде резсприон	Date	Date
1 NDC:54473-335-	85 g in 1 TUBE; Type 0: Not a Combination Product	10/01/2021	



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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)

<b>Establishment</b>			
Name	Address	ID/FEI	Business Operations
Melaleuca, Inc		079711683	manufacture(54473-335)

Revised: 1/2023 Melaleuca, Inc.