

**PAIN-A-TRATE EXTRA STRENGTH PAIN-RELIEVING- 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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**Pain-A-Trate Extra Strength Pain-Relieving Cream**

**Active ingredients**

Camphor 3.25%

Menthol, 1.5%

Methyl Salicylate, 15%

**Purpose**

Topical analgesic

**Uses** for the temporary relief of minor aches and pains of muscles and joints. Provides penetrating pain relief of aches and pains associated with:

- simple backache
- arthritis
- strains
- bruises
- sprains

**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
- 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 generously 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, cetyl alcohol, deionized water, FD and C blue no. 1, FD and C yellow no. 5, glyceryl monostearate SE, Melaleuca Oil (T36-C5<sup>®</sup> brand), polysorbate 20, sorbitan stearate, steric acid, triethanolamine

### Drug Facts

Active ingredients	Purpose
Camphor 3.25%	Topical analgesic
Menthol 1.5%	Topical analgesic
Methyl salicylate 15%	Topical analgesic

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■ simple backache ■ arthritis ■ strains ■ bruises ■ sprains

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- condition worsens or symptoms persist for more than 7 days
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**Inactive ingredients** acrylates/C10-30 alkyl acrylate crosspolymer, benzyl alcohol, cetyl alcohol, deionized water, FD&C blue no. 1, FD&C yellow no. 5, glyceryl monostearate SE, Melaleuca Oil (T36-C5® brand), polysorbate 20, sorbitan stearate, stearic acid, triethanolamine

Melaleuca, Inc.  
Idaho Falls, ID 83402-6003  
To order: 1-800-282-3000  
www.melaleuca.com  
Product of USA #184 07/09U  
NOT FOR RESALE IN CANADA



EXTRA-STRENGTH  
**PAIN-A-TRATE**  
PAIN-RELIEVING CREAM • NET WT. 3 OZ. (85 g)

**Drug Facts (continued)**

**When using this product**

- avoid contact with eyes or mucous 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

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If swallowed, get medical help or contact a Poison Control Center right away.

**Directions**

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

**Drug Facts (continued)**

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

**Inactive ingredients** acrylates C10-30 alkyl acrylate crosspolymer, benzyl alcohol, cetyl alcohol, deionized water, FD&C blue no. 1, FD&C yellow no. 5, glyceryl monostearate SF, Meleuca Oil (384-CSP brand), polysorbate 20, sorbitan stearate, stearic acid, triethanolamine

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**PAIN-A-TRATE**  
EXTRA STRENGTH  
PAIN-RELIEVING CREAM (NET WT 1 OZ (28.3g))

**Drug Facts**

**Active ingredients**

- Camphor 0.5%
- Menthol 1.5%
- Methyl salicylate 15%

**Purpose**

- Topical analgesic
- Topical anesthetic
- Topical analgesic

**Uses** for the temporary relief of minor aches and pains of muscles and joints.  
Provides penetrating pain relief of aches and pains associated with:

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- strains
- bruises
- sprains

**Warnings**

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**PEEL HERE**

## PAIN-A-TRATE EXTRA STRENGTH PAIN-RELIEVING

camphor and menthol and methyl salicylate cream

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:54473-150
<b>Route of Administration</b>	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:O414PZ4LPZ)	METHYL SALICYLATE	150 mg in 1 g

### Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	

<b>GLYCERYL MONOSTEARATE</b> (UNII: 230OU9XXE4)
<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)
<b>CETYL ALCOHOL</b> (UNII: 936JST6JCN)
<b>SORBITAN MONOSTEARATE</b> (UNII: NVZ4I0H58 X)
<b>POLYSORBATE 20</b> (UNII: 7T1F30V5YH)
<b>TEA TREE OIL</b> (UNII: VIF565UC2G)
<b>TROLAMINE</b> (UNII: 9O3K93S3TK)
<b>CARBOMER COPOLYMER TYPE B</b> (UNII: 1G56KV7BUJ)
<b>BENZYL ALCOHOL</b> (UNII: LKG8494WBH)
<b>FD&amp;C BLUE NO. 1</b> (UNII: H3R47K3TBD)
<b>FD&amp;C YELLOW NO. 5</b> (UNII: I753WB2F1M)

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54473-150-03	85 g in 1 TUBE; Type 0: Not a Combination Product	01/01/2018	
2	NDC:54473-150-01	28 g in 1 TUBE; Type 0: Not a Combination Product	01/01/2018	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	05/01/2007	

**Labeler** - Melaleuca, Inc. (139760102)

### Establishment

Name	Address	ID/FEI	Business Operations
Melaleuca, Inc		079711683	manufacture(54473-150)

Revised: 3/2020

Melaleuca, Inc.