# 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.

-----

#### 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**

Purpose ..Topical analgesic ..Topical analgesic Methyl salicylate 15%. .Topical analgesic

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

simple backache = arthritis = straips = bruises = sprains

## Warnings For external use only

#### Do not use

- on wounds or damaged skin
- with a heating pad I with a heating pad I 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 ase 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 generously to affected area with gentle massage do not apply more than 3 to 4 times daily

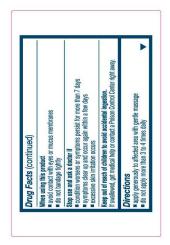
Other information do not store above 95°F (35°C)

Inactive ingredients acytates/C10-30 alkyl acytate crosspolymer, berzyl alcohol, cetyl alcohol, delonized water, FD&C blue no. 1, FD&C yellow no. 5, glyceryl monostearate SE, Melaleuca OI (T36-C5° brand), polysorbate 20, sorbitan stearate, stearic acid, trieffanolamine

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 GANADA



CREAM: NET WE. 8 OE. (85g)





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

camphor and menthol and methyl salicylate cream

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:54473-150	
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: L7T10 EIP3A) (MENTHOL - UNII:L7T10 EIP3A)	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: 059QF0KO0R)		

GLYCERYL MONOSTEARATE (UNII: 230 O U9 XXE4)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
SORBITAN MONOSTEARATE (UNII: NVZ4I0 H58 X)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
TEA TREE OIL (UNII: VIF565UC2G)	
TROLAMINE (UNII: 9O3K93S3TK)	
CARBOMER COPOLYMER TYPE B (UNII: 1G56KV7BUJ)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	

F	Packaging				
#	Item Code	Package Description	<b>Marketing Start Date</b>	Marketing End Date	
1	NDC:54473-150-03	85 g in 1 TUBE; Type 0: Not a Combination Product	0 1/0 1/20 18		
2	NDC:54473-150-01	28 g in 1 TUBE; Type 0: Not a Combination Product	0 1/0 1/20 18		

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.