

**PAIN EASE- camphor, menthol, methyl salicylate lotion**  
**PUREVIVE HEALTH SCIENCES**

*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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**ACTIVE INGREDIENTS**

CAMPBOR 2.8% W/V

MENTHOL 8.8% W/V

METHYL SALICYLATE 28% W/V

**PURPOSE**

External Analgesic, Relives minor aches and pains

**USES**

TEMPORARILY RELIEVES:

- ARTHRITIS PAIN
- SORE MUSCLES
- BACKACHES

**WARNINGS**

FOR EXTERNAL USE ONLY.

DO NOT USE IF

- SAFETY SEAL IS BROKEN, OR HAS BEEN TAMPERED WITH

STOP USE AND ASK A PHYSICIAN IF

- SYMPTOMS PERSIST FOR MORE THAN 7 DAYS
- SYMPTOMS CLEAR UP AND OCCUR AGAIN WITHIN A FEW DAYS
- CONDITION WORSENS

WHEN USING THIS PRODUCT

- AVOID CONTACT WITH EYES, MOUTH, GENITALIA AND BROKAN SKIN
- DO NOT APPLY TO WOUNDS OR DAMAGED SKIN
- DO NOT BANDAGE OR APPLY EXTERNAL HEAT TO AFFECTED AREA

**OTHER INFORMATION**

- KEEP CAP TIGHTLY CLOSED

KEEP OUT OF REACH OF CHILDREN. IN CASE OF ACCIDENTAL INGESTION, GET MEDICAL HELP OR CONTACT A POISON CONTROL CENTER RIGHT AWAY.

**DIRECTIONS**

- APPLY LOTION TO PAINFUL AREA
- RUB INTO SKIN
- REPEAT AS NEEDED

ADULTS AND CHILDREN 12 YEARS AND OLDER - USE AS DIRECTED

CHILDREN UNDER 12 YEARS - DO NOT USE

**INACTIVE INGREDIENTS**

Carthamus Tinctorius (Safflower) Oil, Ceteth 20, Cetyl Alcohol, Disodium EDTA, Fragrance, Glyceryl Stearate, Isopropyl Myristate, Lecithin, Magnesium Aluminum Silicate, Methylparaben, PEG-75 Stearate, PEG-100 Stearate, Polaxamer 407, Propylparaben, SDA 40-B, Steareth 20, Stearic Acid, Triethanolamine, Water.

**Drug Facts**

**Active Ingredients**

Camphor	2.8% w/v
Menthol	8.8% w/v
Methyl Salicylate	28% w/v

**Purpose**  
External Analgesic, Relieves minor aches and pains

**Uses** temporarily relieves:

- arthritis pain   ■ sore muscles
- backaches

**Warnings**  
For external use only

**Do not use if**

- safety seal is broken, or has been tampered with

**Stop use and ask a physician if**

- symptoms persist for more than 7 days
- symptoms clear up and occur again within a few days
- condition worsens

**When using this product**

- avoid contact with eyes, mouth, genitalia and broken skin
- do not apply to wounds or damaged skin
- do not bandage or apply external heat to affected area

300-2



**PAIN  
EASE**

Topical Pain Relief Lotion

For External Use Only

**2 fl. oz. (59ml)**

**THP**  
Los Alamitos, CA 90702  
**1-800-749-3937**

**Drug Facts (continued)**

**Keep out of reach of children.** In case of accidental ingestion, get medical help or contact a Poison Control Center right away.

**Directions**

- Apply lotion to painful area
- Rub into skin
- Repeat as needed

adults and children 12 years and older	use as directed
children under 12 years	do not use

**Other Information**

- Keep cap tightly closed

**Inactive ingredients**

Carthamus Tinctorius (Safflower) Oil, Ceteth 20, Cetyl Alcohol, Disodium EDTA, Fragrance, Glyceryl Stearate, Isopropyl Myristate, Lecithin, Magnesium Aluminum Silicate, Methylparaben, PEG-75 Stearate, PEG-100 Stearate, Polaxamer 407, Propylparaben, SDA 40-B, Steareth 20, Stearic Acid, Triethanolamine, Water.

**PAIN EASE**

camphor, menthol, methyl salicylate lotion

**Product Information**

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71646-104
Route of Administration	TOPICAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
CAMPHOR OIL (UNII: 75IZZ8 Y727) (CAMPHOR OIL - UNII:75IZZ8 Y727)	CAMPHOR OIL	2.8 g in 100 mL

<b>MENTHOL</b> (UNII: L7T10EP3A) (MENTHOL - UNII:L7T10EP3A)	MENTHOL	8.8 g in 100 mL
<b>METHYL SALICYLATE</b> (UNII: LAV5U5022Y) (SALICYLIC ACID - UNII:O414PZ4LPZ)	METHYL SALICYLATE	28 g in 100 mL

### Inactive Ingredients

Ingredient Name	Strength
<b>SAFFLOWER OIL</b> (UNII: 65UEH262IS)	
<b>CETETH-20</b> (UNII: I835H2IHHX)	
<b>CETYL ALCOHOL</b> (UNII: 936JST6JCN)	
<b>EDETATE DISODIUM</b> (UNII: 7FLD91C86K)	
<b>GLYCERYL MONOSTEARATE</b> (UNII: 230OU9XXE4)	
<b>ISOPROPYL MYRISTATE</b> (UNII: 0RE8K4LNJS)	
<b>LECITHIN, SOYBEAN</b> (UNII: 1DI56QDM62)	
<b>MAGNESIUM ALUMINUM SILICATE</b> (UNII: 6M3P64V0NC)	
<b>METHYL PARABEN</b> (UNII: A2I8C7HI9T)	
<b>PEG-75 STEARATE</b> (UNII: OT38R0N74H)	
<b>PEG-100 STEARATE</b> (UNII: YD01N1999R)	
<b>POLOXAMER 407</b> (UNII: TUF2IVW3M2)	
<b>PROPYL PARABEN</b> (UNII: Z8IX2SC1OH)	
<b>ALCOHOL</b> (UNII: 3K9958V90M)	
<b>STEARETH-20</b> (UNII: L0Q8IK9E08)	
<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)	
<b>TROLAMINE</b> (UNII: 9O3K93S3TK)	
<b>WATER</b> (UNII: 059QF0KO0R)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71646-104-11	59 mL in 1 BOTTLE; Type 0: Not a Combination Product	12/14/2017	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	12/14/2017	

**Labeler** - PUREVIVE HEALTH SCIENCES (080596378)

**Registrant** - PUREVIVE HEALTH SCIENCES (080596378)

### Establishment

Name	Address	ID/FEI	Business Operations
Health Specialty		794053863	manufacture(71646-104)