# MENTHOL 10 PERCENT PLUS CAMPHOR 4 PERCENT- menthol and camphor cream Alexso, 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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## **Menthol and Camphor Cream**

Menthol 10% and Camphor 4% Cream Alexso, Inc

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Menthol 10% and Camphor 4% Cream

**Drug Facts** 

## **Active ingredient**

## **Purpose**

Menthol 10%	Topical analgesic
Camphor 4%	Topical analgesic

#### Uses

For the temporary relief of minor aches and pains of muscles and joints, such as simple backache, lumbago, arthritis, neuralgia, strains, bruises, and sprains.

## **Warnings**

For external use only.

## When using this product

- Avoid contact with the eyes
- Do not use in large quantities, particularly over raw surfaces or blistered areas
- Do not apply to wounds or damaged skin
- Do not bandage

## Stop use and ask a doctor if

- allergic reaction occurs
- condition worsens or does not improve within 7 days
- symptoms clear up and return within a few days
- redness, irritation, swelling, pain or other symptoms begin or increase

## Keep out of reach of children.

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

## **Directions**

adults and children 2 years and older	apply externally to the affected area up to 3 to 4 times a day
children under 2 years	ask a doctor

#### Other information

- May be applied under occlusive dressing.
- Store at 20-25°C (68-77°F); excursions permitted to 15-30°C (59-86°F). See USP Controlled Room Temperature.

## **Inactive ingredients**

Aqua (Deionized Water), Arnica Montana Flower Extract, Boswellia Serrata Extract, Cetearyl Alcohol, Chondroitin Sulfate, Glucosamine Sulfate, Glycerin, Glyceryl Caprylate, Glyceryl Stearate, C13-14 Isoparaffin, Isopropyl Alcohol, Isostearyl Palmitate, Laureth-7, Methylsulfonylmethane (MSM), PEG-100 Stearate, Phenoxyethanol, Polyacrylamide, Propylene Glycol, Sodium Polyacrylate, Stearic Acid, Triethanolamine

## Menthol 10% and Camphor 4% Cream

NDC: 50488-0410-1

## 120 grams

Manufactured for: Alexso, Inc Los Angeles, CA 90064

#### PRINCIPAL DISPLAY PANEL

NDC 50488-0410-1 Menthol 10% + Camphor 4% Cream 120 grams Menthol 10% + Camphor 4% Cream

NDC: 50488-0410-1

Manufactured for: Alexso, Inc.
2317 Cotner Avenue Los Angeles, CA 90064
Tel: 888.495.6078

Drug Facts	
Active ingredient	Purpose
Menthol 10%	Topical Analgesic
Camphor 4%	Topical Analgesic

#### Uses

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## **MENTHOL 10 PERCENT PLUS CAMPHOR 4 PERCENT**

menthol and camphor cream

#### **Product Information**

Product Type HUMAN OTC DRUG Item Code (Source) NDC:50488-0410

Route of Administration TOPICAL

## **Active Ingredient/Active Moiety**

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Ingredient Name	Basis of Strength	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	10 g in 100 g
CAMPHOR (SYNTHETIC) (UNII: 5TJD82A1ET) (CAMPHOR (SYNTHETIC) - UNII:5TJD82A1ET)	CAMPHOR (SYNTHETIC)	4 g in 100 g

## **Inactive Ingredients**

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
ARNICA MONTANA FLOWER (UNII: OZ0E5Y15PZ)	
INDIAN FRANKINCENSE (UNII: 4PW41QCO2M)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
CHONDROITIN SULFATE (BOVINE) (UNII: 6IC1M3OG5Z)	

GLUCOSAMINE SULFATE (UNII: 1FW7WLR731)	
GLYCERIN (UNII: PDC6A3C0OX)	
GLYCERYL CAPRYLATE (UNII: TM2TZ D4G4A)	
GLYCERYL MONOSTEARATE (UNII: 2300U9XXE4)	
C13-14 ISOPARAFFIN (UNII: E4F12ROE70)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
ISOSTEARYL PALMITATE (UNII: 9EHU0R7ER1)	
LAURETH-7 (UNII: Z95S6G8201)	
DIMETHYL SULFONE (UNII: 9H4PO4Z4FT)	
PEG-100 STEARATE (UNII: YD01N1999R)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
POLYACRYLAMIDE (10000 MW) (UNII: E2KR9C9V2I)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SODIUM POLYACRYLATE (8000 MW) (UNII: 285CYO341L)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TROLAMINE (UNII: 903K93S3TK)	

l	Packaging				
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
		NDC:50488- 0410-1	120 g in 1 BOTTLE; Type 0: Not a Combination Product	09/01/2019	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part348	09/01/2019	

## **Labeler -** Alexso, Inc (963338061)

Revised: 10/2022 Alexso, Inc