MENTHOL- menthol 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.

Menthol Cream

Menthol 4% Cream
Alexso, Inc

Menthol 4% Cream

Drug Facts

Active ingredient

Menthol 4%

Purpose

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	apply externally to the affected area up to 3 to

and older	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, Ethylhexylglycerin, Glucosamine Sulfate, Glycerin, 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 4% Cream

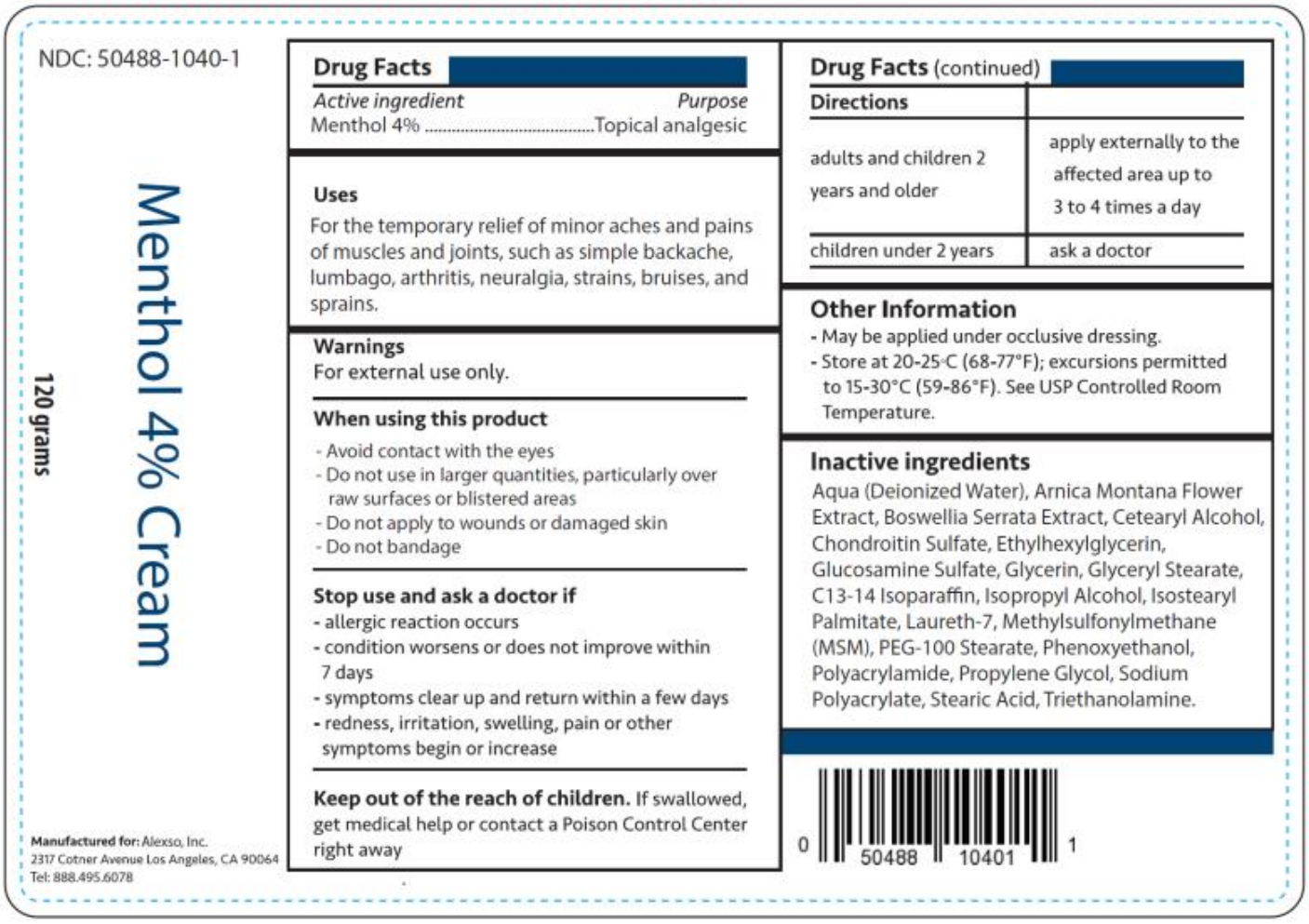
NDC: 50488-1040-1

120 grams

Manufactured for:
Alexso, Inc
Los Angeles, CA 90064

PRINCIPAL DISPLAY PANEL

NDC 50488-1040-1
Menthol 4% Cream
120 grams



MENTHOL

menthol cream

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:50488-1040
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	40 mg in 1 g

Inactive Ingredients	
Ingredient Name	**Strength**
WATER (UNII: 059QF0KO0R)	
ARNICA MONTANA FLOWER (UNII: OZ0E5Y15PZ)	
INDIAN FRANKINCENSE (UNII: 4PW41QCO2M)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
GLUCOSAMINE SULFATE (UNII: 1FW7WLR731)	

GLYCERIN (UNII: PDC6A3C0OX)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
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)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TROLAMINE (UNII: 9O3K93S3TK)	
CHONDROITIN SULFATE (BOVINE) (UNII: 6IC1M3OG5Z)	
SODIUM POLYACRYLATE (8000 MW) (UNII: 285CYO341L)	
POLYACRYLAMIDE (10000 MW) (UNII: E2KR9C9V2I)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50488-1040-1	120 g in 1 BOTTLE; Type 0: Not a Combination Product	04/01/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part348	04/01/2019	

Labeler - Alexso, Inc (963338061)

Revised: 4/2019 Alexso, Inc