# CALMADOL- camphor, menthol, methyl salicylate liniment GRANDALL DISTRIBUTING, LLC

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#### Grandall (as PLD) - CALMADOL OINTMENT (48201-004)

**Drug Facts** 

#### **Active Ingredients:**

Camphor 6.00%

Menthol 1.90%

Methyl Salicylate 10.00%

#### **Purpose:**

External Analgesic

#### Uses

For prompt temporary relief of minor aches and pains of muscles and joints associated with:

- simple backache
- arthritis
- strains
- bruises
- sprains

#### Warnings

## For external use only

## When using this product

- Avoid contact with eyes and 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 few days.

If pregnant or breast-feeding, or if you have sensitive skin, ask a healthcare professional before use.

**Keep out of reach of childern.** If swallowed, get medical help or contact a Poison Control Center immediately.

#### Do not use

- on wounds
- on damaged skin
- with heating pad
- on children under 12 years of age

#### **Directions**

- Use only as directed.
- Adults and chridren older than 12 years of age, apply cream to the affected area not more than 3 to 4 trmes daily.
- For children less than 12 years of age: ask a doctor

## **Inactive Ingredients**

Puified Water (Aqua), Stearic Acid, Glyceryl Stearate, Turpentine, Mentha Piperita (Pepperment) Oil, TEA-Lauryl Sulfate, Triethanolamine, Methylparaben, Propylparaben.

## **Package Labeling**

**ARTHRITIS** 

CALMADOL

NET WT. 6 oz (170.1G)



## **CALMADOL**

camphor, menthol, methyl salicylate liniment

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:48201-004	
Route of Administration	TOPICAL			

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
CAMPHOR (NATURAL) (UNII: N20HL7Q941) (CAMPHOR (NATURAL) - UNII:N20HL7Q941)	CAMPHOR (NATURAL)	6 g in 100 g		
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	1.9 g in 100 g		

METHYL SALICYLATE (UNII: LAV5U5022Y) (SALICYLIC ACID - UNII:O414PZ4LPZ) METHYL SALICYLATE 10 g in 100 g

Inactive Ingredients			
Ingredient Name	Strength		
STEARIC ACID (UNII: 4ELV7Z65AP)			
GLYCERYL STEARATE SE (UNII: FCZ5MH785I)			
TURPENTINE (UNII: XJ6RUH0O4G)			
PEPPERMINT OIL (UNII: AV092KU4JH)			
LAURYL SULFATE (UNII: DIQ16UC154)			
TROLAMINE (UNII: 903K93S3TK)			
METHYLPARABEN (UNII: A2I8C7HI9T)			
PROPYLPARABEN (UNII: Z8IX2SC1OH)			

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:48201-004- 17	1 in 1 BOX	07/08/2015		
1		170.1 g in 1 JAR; Type 0: Not a Combination Product			

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC Monograph Drug	M017	07/08/2015		

## Labeler - GRANDALL DISTRIBUTING, LLC (044428324)

Revised: 1/2024 GRANDALL DISTRIBUTING, LLC