

**BON BALM PENETRATING PAIN RELIEF- menthol methyl salicylate oil
PMC TRADE, EXPORT AND IMPORT**

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.

Drug Facts

Active Ingredients

Camphor 6%

Menthol 1.25%

Purpose

External Analgesic

External Analgesic

Uses

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

■ simple backache ■ arthritis ■ strains ■ bruises ■ sprains

Warnings

- **For external use only** ■ Avoid getting into the eyes or on mucous membranes
- Discontinue use if excessive irritation of the skin develops

When using this product

- Do not apply to wound or damaged skin.
- Do not bandage tightly

Stop use and ask a doctor if

- Condition worsens, or if symptoms persist for more than 7 days or clear up and occur again within a few days
- Pain persists for more than 10 days conditions
- Redness is present
- Conditions affect children under 12 years of age

Keep out of reach of children

If swallowed, get medical help or contact a poison control center right away

Directions

- Adults and children 12 years of age and older apply to affected area not more than 3 to 4 time daily

- Apply liberally and gently rub into affected area
- Children under 12 years of age, consult a doctor before using

Inactive ingredients

Grape Seed Oil, Lemon Oil, Pine Needle Oil, Sesame Oil, Sunflower Oil, Sweet Almond Oil

Package Label



BON BALM PENETRATING PAIN RELIEF

menthol methyl salicylate oil

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68973-001
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CAMPHOR (SYNTHETIC) (UNII: 5TJD82A1ET) (CAMPHOR (SYNTHETIC) - UNII:5TJD82A1ET)	CAMPHOR (SYNTHETIC)	6 g in 100 mL
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	1.25 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
GRAPE SEED OIL (UNII: 930MLC8XGG)	
LEMON OIL (UNII: I9GRO824LL)	
PINE NEEDLE OIL (PINUS SYLVESTRIS) (UNII: 5EXL5H740Y)	
SESAME OIL (UNII: QX10HYY4QV)	
SUNFLOWER OIL (UNII: 3W1JG795Y)	
ALMOND OIL (UNII: 66YXD4DKO9)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68973-001-01	1 in 1 BOX		
1	NDC:68973-001-60	60 mL in 1 BOTTLE, GLASS		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	05/15/2014	

Labeler - PMC TRADE, EXPORT AND IMPORT (179635003)

Revised: 6/2014

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