

**PHOENIX BALM - pain relief rub ointment**  
**Amazonian Naturals, 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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**Drug Facts**

**Active Ingredients**

Camphor 5%..... Topical Analgesic  
Menthol 5% ..... Topical Analgesic  
Methyl Salicylate 5%..... Topical Analgesic

**Purposes**

Topical Analgesic

**Uses**

For temporary relief of minor aches and pains of muscles and joints associated with over-exertions, arthritis, strains and sprains.

**Warnings For external use only.**

**When using this product**

- Avoid contact with eyes and mucous membranes.
- Do not apply to open wounds or damaged skin.
- Do not bandage or use heating pad.

**Stop use and ask a doctor if**

- Condition Worsens.
- Severe skin irritation occurs.
- Pain persists for more than seven days.
- Pain clears up and then recurs a few days later.

**If pregnant or breast-feeding** ask a health care professional before use.

**Keep out of reach of children.** If swallowed get medical help or contact a Poisen Control Center immediately.

**Directions**

- Rub well on the affected area. Repeat 2 or 3 times daily.
- For children 2 - 12 years, consult a doctor before use.

**Other Information**

This product may cause allergic reaction in some people. Test on small area before use.

**Inactive Ingredients**

Pine needle oil, Cats Claw and Paraffin Petrolatum



## PHOENIX BALM

pain relief rub ointment

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:24438-001
Route of Administration	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
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<b>CAMPHOR (NATURAL)</b> (UNII: N20HL7Q941) (CAMPHOR (NATURAL) - UNII:N20HL7Q941)	CAMPHOR (NATURAL)	50 mg in 1 g
<b>MENTHOL</b> (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	50 mg in 1 g
<b>METHYL SALICYLATE</b> (UNII: LAV5U5022Y) (METHYL SALICYLATE - UNII:LAV5U5022Y)	METHYL SALICYLATE	50 mg in 1 g

### Inactive Ingredients

Ingredient Name	Strength
<b>PINE NEEDLE OIL (PINUS SYLVESTRIS)</b> (UNII: 5EXL5H740Y)	
<b>CAT'S CLAW</b> (UNII: 9060PRM18Q)	
<b>PETROLATUM</b> (UNII: 4T6H12BN9U)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:24438-001-02	1 in 1 BOX		
1	NDC:24438-001-01	19 g in 1 CONTAINER		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part348	12/01/2011	

**Labeler** - Amazonian Naturals, Inc. (969562011)

**Registrant** - Amazonian Naturals, Inc. (969562011)

### Establishment

Name	Address	ID/FEI	Business Operations
Amazonian Naturals, Inc.		969562011	relabel

### Establishment

Name	Address	ID/FEI	Business Operations
Access Trading, SAC		953434516	manufacture

Revised: 11/2011

Amazonian Naturals, Inc.