

POWER RELIEF- menthol gel
Clientele, 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.

POWERRELIEF™
COOLING PAIN RELIEF ROLL ON

Drug Facts

Active Ingredients

Menthol 2%

Purpose

Topical analgesic

Indications

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

- arthritis
- simple backache
- strains
- sprains
- bruises

Warnings

- For external use only.
- Avoid contact with the eyes.
- If condition worsens, or if symptoms persist for more than 7 days or clear up and occur again within a few days, discontinue use of this product and consult a Physician.
- Do not apply to wounds or damaged skin.
- Do not bandage tightly.
- **Keep out reach of children.** If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- Adults and children 2 years of age and older:
apply to affected area not more than 3 to 4 times daily.
- Children under 2 years of age, consult a Physician.

Inactive Ingredients

Water, Butylene Glycol, Aloe Barbadensis Leaf Juice, Eucalyptus Globulus Leaf Oil, Methyl

Salicylate, Camphor, Mentha Piperita (Peppermint) Oil, Carbomer, Triethanolamine, Propylparaben, Methylparaben, Diazolidinyl Urea, Tetrasodium EDTA.

Distributed exclusively by
American Herbal Products Corp.
 North Bay Village, Florida

PRINCIPAL DISPLAY PANEL - 59.1 ml Bottle Label

POWERRELIEF™
COOLING PAIN RELIEF ROLL ON

Net wt. 2 fl.oz (59.1 ml)
MADE IN USA



POWER RELIEF			
menthol gel			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:64483-007
Route of Administration	TOPICAL		
Active Ingredient/Active Moiety			
	Ingredient Name	Basis of Strength	Strength
	Menthol (UNII: L7T10EIP3A) (Menthol - UNII:L7T10EIP3A)	Menthol	2 mL in 100 mL
Inactive Ingredients			
	Ingredient Name	Strength	
	Camphor (Synthetic) (UNII: 5TJD82A1ET)	0.52 mL in 100 mL	
	Water (UNII: 059QF0KO0R)	84.61 mL in 100 mL	

Eucalyptus oil (UNII: 2R04ONI662)

0.81 mL in 100 mL

Product Characteristics

Color	YELLOW	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:64483-007-02	59 mL in 1 BOTTLE, WITH APPLICATOR		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	04/02/2004	

Labeler - Clientele, Inc. (085021806)

Revised: 9/2011

Clientele, Inc.