SOOTHING PAIN RELIEF ROLL ON- menthol, unspecified form 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.

Soothing 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 of 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, Silica, Potassium Citrate, Magnesium Carbonate,

Oleic Acid, Carbomer, Triethanolamine, Propylparaben, Methylparaben, Diazolidinyl Urea, Tetrasodium EDTA.

PRINCIPAL DISPLAY PANEL - 59.1 ml Bottle Label

Soothing
Pain Relief

Roll-On

2 Fl Oz (59.1 ml)

Rejuvenetics™

SOOTHING PAIN RELIEF ROLL ON

menthol, unspecified form gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:64483-008
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A) (MENTHOL, UNSPECIFIED FORM - UNII:L7T10EIP3A)	MENTHOL, UNSPECIFIED FORM	2 mg in 100 mL

Inactive Ingredients	
Ingredient Name	**Strength**
Camphor (synthetic) (UNII: 5TJD82A1ET)	0.52 mg in 100 mL
Water (UNII: 059QF0KO0R)	
Eucalyptus oil (UNII: 2R04ONI662)	

Product Characteristics			
Color	YELLOW	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:64483-008-02	59.1 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	03/04/2014	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	03/04/2014	

Labeler - Clientele, Inc. (085021806)

Revised: 12/2019 Clientele, Inc.