K2 COLD THERAPY- menthol liquid
The Podiatree Co

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.

Active ingrdient:

Menthol 10%

PURPOSE

TOPICAL ANALGESIC

TEMPORARILY RELIEVES MINOR PAIN ASSOCIATED WITH:

- ARTHRITIS
- SIMPLE BACKACHE
- MUSCLE STRAINS
- SPRAINS

For external use only.

Flammable; Keep away from fire, sparks and heated surfaces

- Use only as directed
- Do not bandage tighlty or use with a heating pad
- Avoid contact with eyes and mucous membranes
- Do not apply to wounds or damaged, broken, or irritated skin.

- Condition worsens
- Redness is present
- Irritation develops
- Symptoms persist for more than 7 days or clear up and reoccur within a few days

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

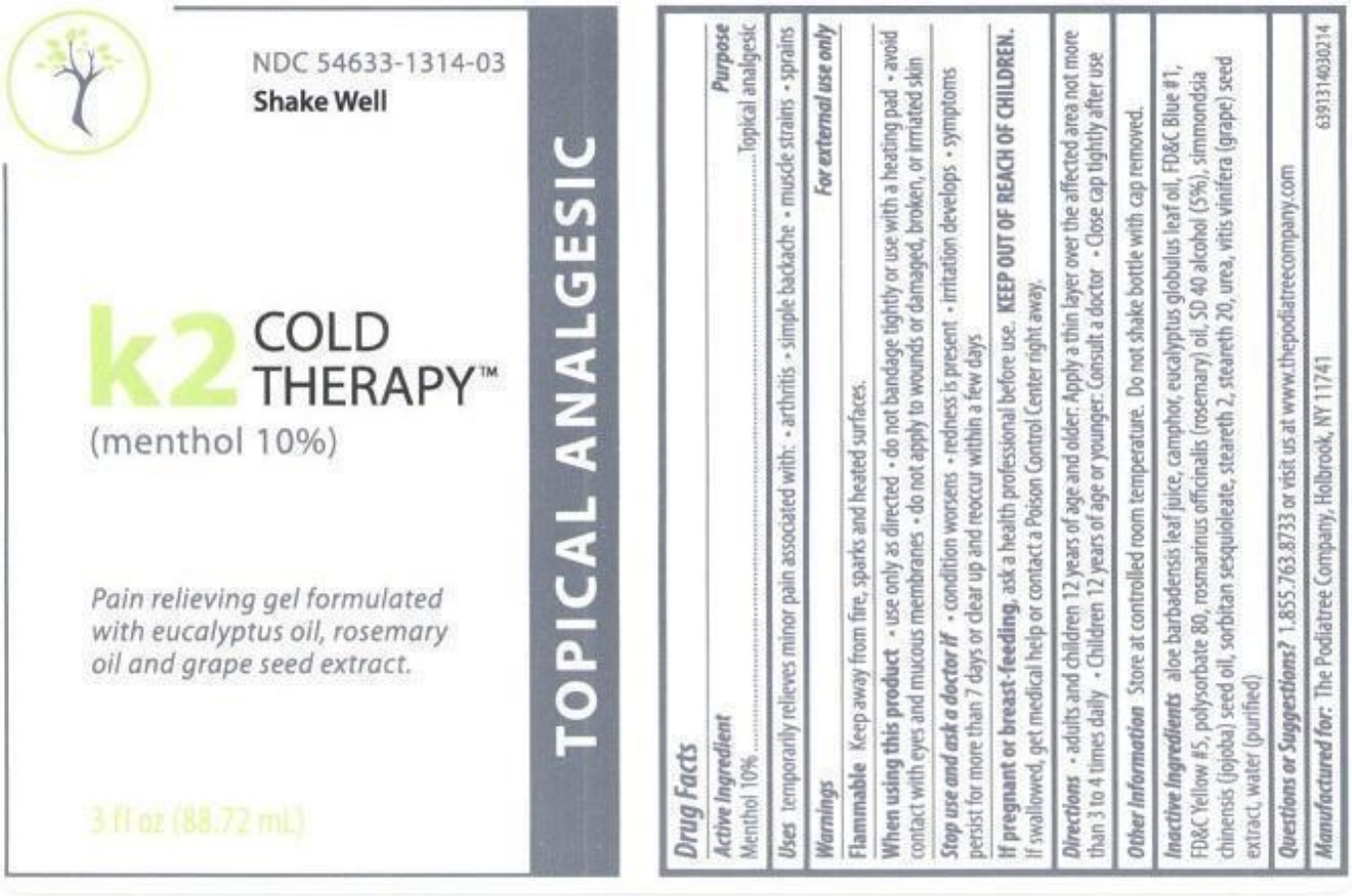
Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

- Adults and children 12 years of age and older: Apply a thin layer over the affected area not more than 3 to 4 times daily.
- Children 12 years of age or younger: Consult a doctor.
- Close cap tightly after use.

Store at controlled room temperature. Do not shake bottle with cap removed.

Aloe Barbadensis Leaf Juice, Camphor, Eucalyptus Globulus Leaf Oil, FD&C Blue #1, FD&C Yellow #5, Polysorbate 80, Rosmarinus Officinalis (Rosemary) Oil, SD 40 Alcohol (5%) Simmondsia Chinensis (Jojoba) Seed Oil, Sorbitan Sesquioleate, Steareth 2, Steareth 20, Urea, Vitis Vinifera (Grape) Seed Extract, Water (Purified)

1.855.763.8733 or visit us at www.thepodiatreecompany.com



K2 COLD THERAPY

menthol liquid

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:54633-201
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	10 g in 100 mL

Inactive Ingredients	
Ingredient Name	**Strength**
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
CAMPHOR (NATURAL) (UNII: N20HL7Q941)	
EUCALYPTUS GLOBULUS LEAF (UNII: S546YLW6E6)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
ROSMARINUS OFFICINALIS WHOLE (UNII: EA3289138M)	
ALCOHOL (UNII: 3K9958V90M)	

SIMMONDSIA CHINENSIS WHOLE (UNII: DFM16KFA82)	
SORBITAN SESQUIOLEATE (UNII: 0W8RRI5W5A)	
STEARETH-2 (UNII: V56DFE46J5)	
STEARETH-20 (UNII: L0Q8IK9E08)	
UREA (UNII: 8W8T17847W)	
VITIS VINIFERA SEED (UNII: C34U15ICXA)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54633-201-13	88.72 mL in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	05/06/2014	

Labeler - The Podiatree Co (078656000)

Establishment

Name	Address	ID/FEI	Business Operations
EMS Contract Packaging		048602791	manufacture(54633-201)

Revised: 4/2014 The Podiatree Co