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

NDC 54633-1314-03 Shake Well	sic	Purpose Topical analgesic	 musde 	For external use only	vith a heating pad - avoid roken, or irmated skin	evelops • symptoms	KEEP OUT OF REACH OF CHILDREN. way.	he affected area not more se cap tightly after use	h cap removed.	af oll, FD&C Blue #1, (5%), simmondsia vinifera (grape) seed	ny.com	6391314030214
COLD THERAPY™ (menthol 10%)	TOPICAL ANALGESIC		d with: - arthritis - simple backache		Flammable Keep away from fire, sparks and heated surfaces. When using this product - use only as directed - do not bandage tightly or use with a heating pad - avoid contact with eves and mucous membranes - do not apply to wounds or damaged, broken, or inmated skin	Stop use and ask a doctor if • condition worsens • redness is present • irritation develops • symptoms persist for more than 7 days or clear up and reoccur within a few days	professional before use. KEEP OUT 0 on Control Center right away.	Directions - 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	Other Information Store at controlled room temperature. Do not shake bottle with cap removed.	Inactive Ingredients aloe barbadensis leaf juice, camphor, eucalyptus globulus leaf oll, FD&C Blue #1, FD&C Yellow #5, polysorbate 80, rosmarinus officinalis (rosemary) oil, 5D 40 alcohol (5%), simmondsia chinensis (jojoba) seed oil, sorbitan sesquioleate, steareth 2, steareth 20, urea, vitis vinifera (grape) seed extract, water (purified)	Questions or Suggestions? 1,855.763.8733 or visit us at www.thepodiatreecompany.com	folbrock, NY 11741
Pain relieving gel formulated with eucalyptus oil, rosemary oil and grape seed extract.	TOPICAL	lent.	temporarily relieves minor pain associated with:		Keep away from fire, sparks and heated surfaces. this product • use only as directed • do not ban yes and mucous membranes • do not apply to w	Stop use and ask a doctor if - condition worsens - redness is presented 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. KEEI If swallowed, get medical help or contact a Poison Control Center right away.	duits and children 12 years of a es daily - Children 12 years of a	ation Store at controlled room	diemts aloe barbadensis leaf ju 5, polysorbate 80, rosmarinus of ba) seed oll, sorbitan sesquioles (purified)	uggestions? 1.855.763.8733 o	Manufactured for: The Podiatree Company, Holbrook, NY 11741
3 fl oz (88.72 mL)	Drug Eachs	Active Ingredient Menthol 10%	Uses temporal	Warnings	Flammable 8 When using the contact with eye	Stop use and a persist for more	If pregnant o	Directions - a than 3 to 4 time	Other Informu	Inactive Ingredients a FD&C Yellow #5, polysor chinensis (jojoba) seed extract, water (purified)	Questions or 5	Manufactures

nenthol liquid				
Product Information				
Product T ype	HUMAN OTC DRUG	Item Code (Sou	rce)	NDC:54633-201
Route of Administration	TOPICAL			
Active Ingredient/Active	· · · · · · · · · · · · · · · · · · ·			
Ingredient Name			isis of Strength	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)			0	0
MENTHOL (UNII: L7T10EIP3A) (•	MENT	•	10 g in 100 mL
	•		•	
	•		•	
Inactive Ingredients	MENTHOL - UNII:L7T10EIP3A) Ingredient Name		•	10 g in 100 mL
Inactive Ingredients ALOE VERA LEAF (UNII: ZY81Z	MENTHOL - UNII:L7T10EIP3A) Ingredient Name 83H0X)		•	10 g in 100 mL
Inactive Ingredients ALOE VERA LEAF (UNII: ZY8 1Z CAMPHOR (NATURAL) (UNII: N	MENTHOL - UNII:L7T10EIP3A) Ingredient Name 83H0X) V20HL7Q941)		•	10 g in 100 mL
Inactive Ingredients ALOE VERA LEAF (UNII: ZY81Z CAMPHOR (NATURAL) (UNII: N EUCALYPTUS GLOBULUS LEA	MENTHOL - UNII:L7T10EIP3A) Ingredient Name 8 3H0 X) 120 HL7Q941) AF (UNII: S546 YLW6E6)		•	10 g in 100 mL
Inactive Ingredients ALOE VERA LEAF (UNII: ZY8 1Z CAMPHOR (NATURAL) (UNII: N EUCALYPTUS GLOBULUS LEA FD&C BLUE NO. 1 (UNII: H3R47)	Ingredient Name 83H0 X) 20 HL7Q941) 4F (UNII: S546 YLW6E6) K3TBD)		•	10 g in 100 mL
Inactive Ingredients ALOE VERA LEAF (UNII: ZY8 1Z CAMPHOR (NATURAL) (UNII: N EUCALYPTUS GLOBULUS LEA FD&C BLUE NO. 1 (UNII: H3R47 FD&C YELLOW NO. 5 (UNII: 175	MENTHOL - UNII:L7T10EIP3A) Ingredient Name 8 3H0 X) N20 HL7Q941) NF (UNII: S546 YLW6E6) K3TBD) 53WB2F1M)		•	10 g in 100 mL
MENTHOL (UNII: L7T10EIP3A) (Inactive Ingredients ALOE VERA LEAF (UNII: ZY81Z CAMPHOR (NATURAL) (UNII: N EUCALYPTUS GLOBULUS LEA FD&C BLUE NO. 1 (UNII: H3R47 FD&C YELLOW NO. 5 (UNII: 175 POLYSORBATE 80 (UNII: 60ZF ROSMARINUS OFFICINALIS W	Ingredient Name 8 3H0 X) V20 HL7Q941) AF (UNII: S546 YLW6E6) K3TBD) 53WB2F1M) 239ZG8 H)		•	10 g in 100 mL

SI	SIMMONDSIA CHINENSIS WHOLE (UNII: DFM16KFA82)									
s	SORBITAN SESQUIOLEATE (UNII: 0 W8 RRI5W5A)									
SI	STEARETH-2 (UNII: V56DFE46J5)									
SI	STEARETH-20 (UNII: L0Q8IK9E08)									
U	UREA (UNII: 8W8T17847W)									
V	VITIS VINIFERA SEED (UNII: C34U15ICXA)									
W	WATER (UNII: 059QF0K00R)									
	Packaging									
P	ackaging									
P #	ackaging Item Code	Package Description	Marketing	Start Date	Mar	rketing End Date				
#	0 0	Package Description 88.72 mL in 1 BOTTLE	Marketing	Start Date	Mar	rketing End Date				
#	Item Code	U	Marketing	Start Date	Mar	rketing End Date				
#	Item Code	88.72 mL in 1 BOTTLE	Marketing	Start Date	Mar	rketing End Date				
# 1	Item Code NDC:54633-201-13	88.72 mL in 1 BOTTLE		Start Date Marketing Star		rketing End Date Marketing End Date				
# 1	Item Code NDC:54633-201-13	88.72 mL in 1 BOTTLE								

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