

## **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.*

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### **Active ingredient:**

Menthol 10%

### **Purpose**

Topical Analgesic

### **Uses**

TEMPORARILY RELIEVES MINOR PAIN ASSOCIATED WITH:

- ARTHRITIS
- SIMPLE BACKACHE
- MUSCLE STRAINS
- SPRAINS

### **Warnings**

For external use only.

### **When using this product**

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

### **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.

### **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 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)

### Questions or Suggestions?

1.855.763.8733 or visit us at [www.thepodiatreecompany.com](http://www.thepodiatreecompany.com). Our commitment to you is 100% satisfaction. If you are not completely satisfied, please contact us for a full refund.

NDC 54633-414-03  
Shake Well

**k2** COLD THERAPY®  
(menthol 10%)

*Pain relieving gel formulated with eucalyptus oil, rosemary oil and grape seed extract.*

3 fl oz (88.72 mL)

**TOPICAL ANALGESIC**

<b>Drug Facts</b>	<b>Purpose</b> Topical analgesic
<b>Active Ingredient</b> Menthol 10%	
<b>Uses</b> temporarily relieves minor pain associated with: • arthritis • simple backache • muscle strains • sprains	
<b>Warnings</b> <b>For external use only</b>	
<b>When using this product</b> • use only as directed • do not bandage tightly or use with a heating pad • avoid contact with eyes and mucous membranes • do not apply to wounds or damaged, broken, or irritated skin	
<b>Stop use and ask a doctor if</b> • condition worsens • redness is present • irritation develops • symptoms persist for more than 7 days or clear up and reoccur within a few days	
<b>If pregnant or breast-feeding</b> , ask a health professional before use. <b>KEEP OUT OF REACH OF CHILDREN.</b> If swallowed, get medical help or contact a Poison Control Center right away.	
<b>Directions</b> • 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	
<b>Other Information</b> Store at controlled room temperature. Do not shake bottle with cap removed.	
<b>Inactive Ingredients</b> 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)	
<b>Questions or Suggestions?</b> 1.855.763.8733 or visit us at <a href="http://www.thepodiatreecompany.com">www.thepodiatreecompany.com</a> . Our commitment to you is 100% satisfaction. If you are not completely satisfied, please contact us for a full refund.	
<b>Manufactured for:</b> The Podiatree Company, Holbrook, NY 11741	639414031207

## K2 COLD THERAPY

menthol liquid

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:54633-414
<b>Route of Administration</b>	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: HBR47K3TBD)	
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: 059QF0K00R)	

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54633-414-03	88.72 mL in 1 BOTTLE, WITH APPLICATOR; Type 0: Not a Combination Product	05/06/2014	

**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)