HAN KEE IN COOL- menthol gel Globalworks company. Co., Ltd.

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 INGREDIENT

Active ingredients: Menthol 2.0%

INACTIVE INGREDIENT

Inactive ingredients:

Water, Isopropyl Alcohol, Glycerin, Camphor, Glycyrrhiza Inflata Root Extract, Methylsulfonylmethane, Carbomer, PEG-60 Hydrogenated Caster Oil, Methylparaben, Sodium Hydroxide, FD&C blue #1, Flavoring

PURPOSE

Purpose: Topical Analgesic

WARNINGS

Warnings:

Use only as directed.

For external use only.

Avoid contact with the eyes. Do not apply to wounds or damaged skin.

Do not apply to irritated skin or if excessive irritation develops.

Store at room temperature with lid closed tightly.

Keep away from excessive heat or open flame.

Do not use with heating pads or devices.

Keep out of reach of children

KEEP OUT OF REACH OF CHILDREN

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Uses

Uses:

Cool gel is specially formulated for the temporary activation from muscle and joint stiffness through cooling and refreshing effect. It is patented for the formulation, which contains Menthol, Camphor, and Glycyrrhiza Glabra Root Extract, Methyl sulfonyl methane. Patient response to ultrasound and sports massage therapy is enhanced when Cool gel is used to help prior to the ultrasound and massage treatments.

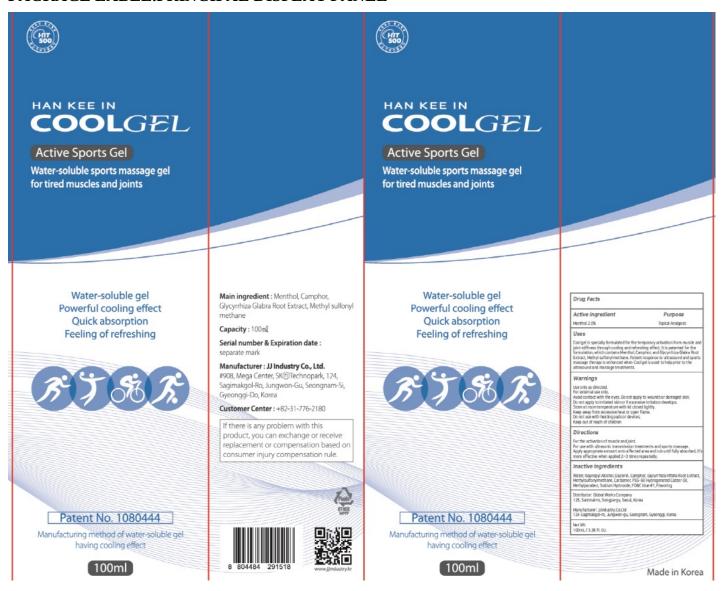
Directions

Directions:

For the activation of muscle and joint.

For use with ultrasonic transmission treatments and sports massage. Apply appropriate amount onto affected area and rub until fully absorbed. It's more effective when applied 2~3 times repeatedly.

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL



HAN KEE IN COOL

menthol gel

Product Type HUMAN	OTC DRUG	Itaan Cada (Canana)	
	, ore bried	Item Code (Source)	NDC:74353-010
Route of Administration TOPICA	AL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
Menthol (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	Menthol	2.0 g in 100 mL	

Inactive Ingredients			
Ingredient Name	Strength		
Water (UNII: 059QF0KO0R)			
Isopropyl Alcohol (UNII: ND2M416302)			
Glycerin (UNII: PDC6A3C0OX)			

I	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:74353-010- 02	1 in 1 CARTON	03/01/2020		
1	NDC:74353-010- 01	100 mL in 1 CONTAINER; Type 0: Not a Combination Product			

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part348	03/01/2020		

Labeler - Globalworks company. Co., Ltd. (695790020)

Registrant - Globalworks company. Co., Ltd. (695790020)

Establishment					
Name	Address	ID/FEI	Business Operations		
JJindustry.Co.Ltd		689605084	manufacture(74353-010)		

Revised: 4/2020 Globalworkscompany. Co., Ltd.