HOT ICE SOOTHING ANALGESIC GEL- menthol gel
Kim Chemicals 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.

Hot Ice Soothing Analgesic Gel

Active Ingredients

Menthol 1.0%

Purpose

Topical Analgesic

Uses

Provides temporary relief of minor aches and pains in muscles and joints associated with simple backache strains, sprains, arthritis and sports injuries

Warnings

For external use only. Not for internal use.

Use only as directed. Avoid contact with eyes or mucous membranes. Do not apply to open wounds or damaged skin. Make sure skin is clean and free from any creams, ointments, sprays or liniment. Do not bandage.

Do not use with heating pads or heating devices.

It condition worsens or symptoms persist for more than 7 days or if symptoms disappear and occur again within a few days, discontinue use and consult a physician. If you have sensitive skin, consult a physician before use. If skin irritation develops, discontinue use and consult a physician. If you are pregnant or nursing a baby, consult your doctor before use. Do not use, store, pour or spill near heat or open flame. Store in a cool, dry place and keep lid tightly closed.

Directions

Clean skin of all other lotions, creams, ointments, liniment or sprays. Apply liberally to affected area and massage until gel is absorbed into skin. Do not apply more than 3 or 4 times daily. No protective cover needed. Do not apply to children under 2 years of age.

Other Ingredients

Water, Isopropyl Alcohol, Nonoxynol-10, Camphor, Carbomer, Sodium Hydroxide, Methylchloroisothiazolinone & Methylisothiazolinone, Blue 1

Principal Display Panel

Perfect Purity

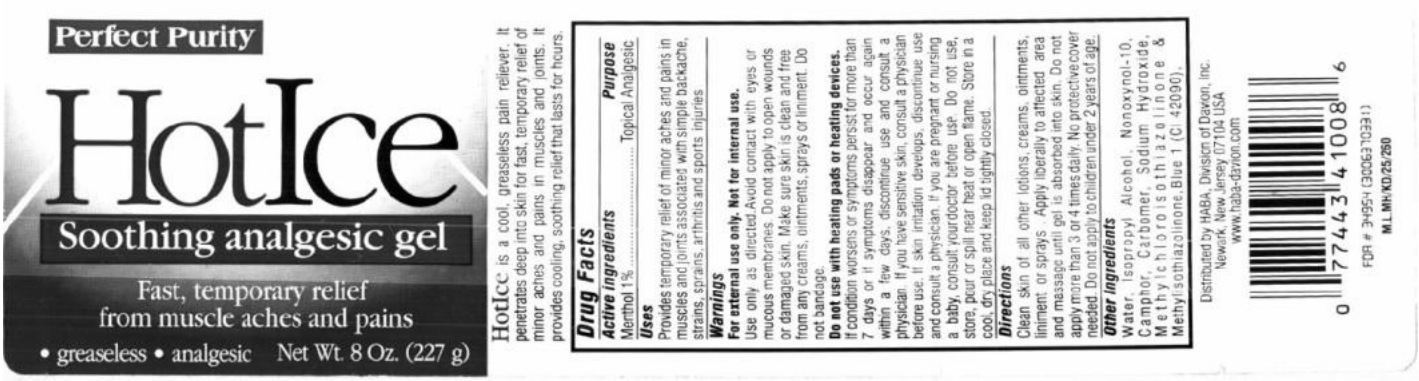
HotIce

Soothing analgesic gel

Fast, temporary relief from muscle aches and pains

- greaseless
- analgesic

NET WT. 8 OZ. (227 g)



HOT ICE SOOTHING ANALGESIC GEL

menthol gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:34954-013
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	2.27 g in 227 g

Inactive Ingredients	
Ingredient Name	**Strength**
WATER (UNII: 059QF0KO0R)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
CAMPHOR (UNII: 5TJD82A1ET)	
CARBOMER 934 (UNII: Z135WT9208)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:34954-013-07	227 g in 1 JAR		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part341	09/21/2009	

Labeler - Kim Chemicals LTD (650470164)

Revised: 9/2009 Kim Chemicals LTD