HIELO ARDIENTE- menthol gel
Menper Distributors, Inc.

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

Menthol 1%

Purpose

Analgesic

Warnings

- For external use only
- Do not use if condition worsens
- If symptoms persist for more than 5 days or recur, discontinue use and consult a physician
- Do not apply to open wounds or damaged skin
- Do not bandage tightly
- Do not use with heating pads or heating devices
- Avoid contact with eyes

Use only as directed

Keep out of reach of children.

In case of accidental ingestion, contact a doctor or a Poison Control Center right away.

Directions

- **Adults and children 12 years of age or older:** Apply to affected area no more than 3 to 4 times daily. Children under 12 years of age, consult a physician
- Cleanse and dry skin. May be used with wet or dry bandages in conjuction with ice packs.

Other information

- store this product between 15°-30°C (59°-86°F)

Inactive ingredients

camphor, carbomer 940, FD&C blue #1, isopropyl alcohol, methylchloroisothiazolinone, polysorbate 20, purified water, triethanolamine

HIELO ARDIENTE

menthol gel

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:53145-002
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	4840 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
CAMPHOR (SYNTHETIC) (UNII: 5TJD82A1ET)	
CARBOMER 940 (UNII: 4Q93RCW27E)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
METHYLCHLOROISOTHIAZOLINONE (UNII: DEL7T5QRPN)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
WATER (UNII: 059QF0KO0R)	
TRIETHANOLAMINE BENZOATE (UNII: M3EN4GC19W)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53145-002-01	1 in 1 CARTON		
1		484 g in 1 JAR		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	02/21/2012	

Labeler - Menper Distributors, Inc. (101947166)