COOL HOT ICE ANALGESIC GEL- menthol gel
SHIELD LINE LLC

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 1.0%

Purpose

Topical Analgesic

***Uses*:**

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

Warnings

FOR EXTERNAL USE ONLY

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

If 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 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 spoll near heat or open flame. Store in a cool, dry place and keep lid tightly closed.

In case of accidental ingestion, get medical help or contact a Poison Control Center right away

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 or age.

Inactive Ingredients

Water, Isopropyl Alchohol , Nonoxynol-10, Camphor, Carbomer 934, Sodium Hydroxide, Methylchloroisothiazolinone & Methylisothiazolinone, FD&C Blue no. 1

COOL HOT ICE ANALGESIC GEL

menthol gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:52410-0201
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**
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
NONOXYNOL-10 (UNII: K7O76887AP)	
CAMPHOR (SYNTHETIC) (UNII: 5TJD82A1ET)	
CARBOMER 934 (UNII: Z135WT9208)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
METHYLCHLOROISOTHIAZOLINONE (UNII: DEL7T5QRPN)	
METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
WATER (UNII: 059QF0KO0R)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:52410-0201-2	227 g in 1 JAR; Type 0: Not a Combination Product	09/21/2009	

Marketing Information

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

Labeler - SHIELD LINE LLC (078518916)

Revised: 5/2019 SHIELD LINE LLC