

KOOL COMFORT - menthol gel
Dee Cee Laboratories, 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.

Kool Comfort

Active ingredient

Menthol 2.5%

Purpose

Cooling Pain relief

Uses

For the temporary relief of minor aches and pains of muscles and joints associated with • simple backache • arthritis • strains • bruises • sprains

Warnings

For external use only.

Flammable

Keep away from excessive heat or open flame.

Ask a doctor before use if you have

- sensitive skin

When using this product

- avoid contact with the eyes or mucous membranes
- do not apply to wounds or damaged skin
- do not use with other ointments, creams, sprays or liniments
- do not apply to irritated skin or if excessive irritation develops
- do not bandage
- wash hands after use with cool water
- do not use with heating pad or heating devices

Stop use and ask a doctor if

- condition worsens, or if symptoms persist for more than 7 days or clear up and occur again 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 2 years of age and over:** apply to affected area not more than 3 to 4 times daily
- **Children under 2 years of age:** Consult a physician.

Other information

Store in a cool dry place with lid tightly closed.

Inactive ingredients

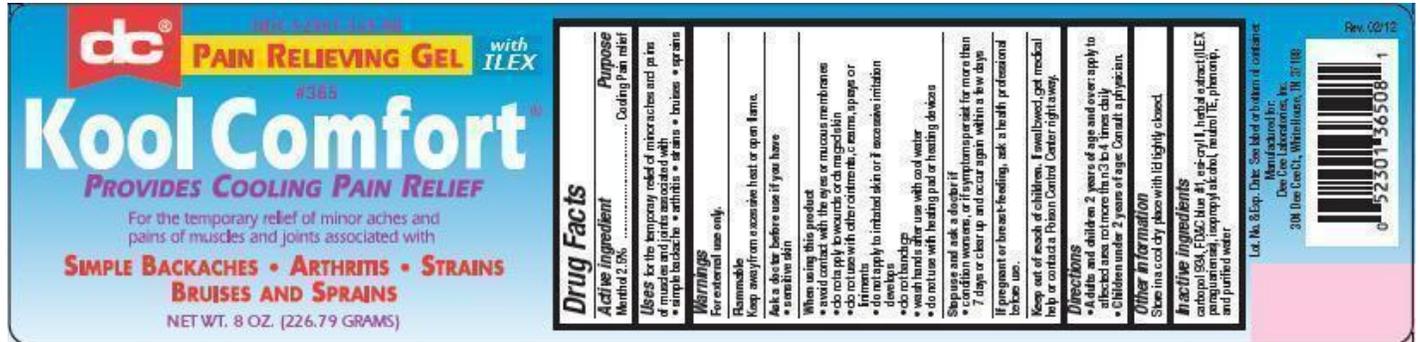
carbopol 934, FD&C blue #1, esi-cryll II, herbal extract (ILEX paraguariensis), isopropyl alcohol, neutrol TE, phenonip, and purified water.

Lot. No. & Exp. Date: See label or bottom of container.

Manufactured for:

Dee Cee Laboratories Inc., 304 Dee Cee Ct., White House, TN 37188

Product Packaging



KOOL COMFORT

menthol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:52301-365
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Menthol (UNII: L7T10EIP3A) (Menthol - UNII:L7T10EIP3A)	Menthol	2.5 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
CARBOMER 934 (UNII: Z135WT9208)	
ILEX PARAGUARIENSIS LEAF (UNII: 1Q953B404F)	
EDETOL (UNII: Q4R969U9FR)	
WATER (UNII: 059QF0K00R)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:52301-365-08	226.79 g in 1 JAR		
2	NDC:52301-365-16	453.59 g in 1 JAR		
3	NDC:52301-365-32	907.20 g in 1 JAR		
4	NDC:52301-365-78	2211.22 g in 1 JAR		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	07/05/2012	

Labeler - Dee Cee Laboratories, Inc. (034731893)

Registrant - Great Southern Laboratories (056139553)

Establishment

Name	Address	ID/FEI	Business Operations
Great Southern Laboratories		056139553	manufacture(52301-365)

Revised: 7/2012

Dee Cee Laboratories, Inc.