REXALL ICE COLD ANALGESIC- menthol gel
Dolgencorp, 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 2%

Purpose

Topical Analgesic

Uses

For the temporary relief of monor aches and pains in muscles and joints associated with:

■ simple backache
■ sprains
■ arthritis
■ strains
■ sports injuries
■ bruises

Warnings

For external use only

Do not use

■ with other topical pain relievers
■ with heating pads or heating devices

When using this product

■ do not use in or near eyes ■ do not apply to wounds or damaged skin ■ do not bandage tightly

Stop use and ask a doctor if

■ condition worsens ■ symptoms last for more than 7 days or clear up and occur again within a few days
■ redness or irritation develops

If pregnant or breast-feeding

ask a health professional before use

Keep out of reach of children

Keep out of reach of children and pets. If swallowed, get medical help or contact a Poison Control Center right away.

Directions

■ clean affected area before applying product ■ adults and children 2 years of age and older: apply to affected area not more than 3 to 4 times daily

Inactive Ingredients

ammonium hydroxide, carbomer, cupric sulphate, FD&C blue no. 1, isopropyl alcohol, magnesium sulphate, sodium hydroxide, thymol, water

Package Label

REXALL ICE COLD ANALGESIC

menthol gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:55910-088
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	2 g in 100 g

Inactive Ingredients	
Ingredient Name	**Strength**
CARBOXYPOLYMETHYLENE (UNII: 0A5MM307FC)	
CUPRIC SULFATE (UNII: LRX7AJ16DT)	
MAGNESIUM SULFATE, UNSPECIFIED (UNII: DE08037SAB)	
THYMOL (UNII: 3J50XA376E)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	

ISOPROPYL ALCOHOL (UNII: ND2M416302)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55910-088-08	227 g in 1 JAR; Type 0: Not a Combination Product	10/01/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	10/01/2018	

Labeler - Dolgencorp, LLC (068331990)

Revised: 10/2018 Dolgencorp, LLC