COLD THERAPY PAIN RELIEF MEIJER- menthol 4% gel Meijer

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.

Drug Facts

Active ingredient	Purpose
Menthol 4%	Topical Analgesic

Uses

Temporary relief of minor aches and pains of muscles and joints associated with arthritis, simple backache, strains and sprains

Warnings

For external use only.

When using this product • avoid contact with the eyes or mucous membranes • do not apply to wounds or damaged skin • do not apply to the irritated skin or if excessive irritation develops • do not bandage • do not use with heating pad or device 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 breastfeeding ask a health professional before use

Keep out of reach of children. If accidentally ingested get medical help or contact a Poison Control Center immediately.

Directions

- Adults and children 12 years of age and older: Apply on to the affected areas not more than 3-4 times daily.
- Children under 12 years of age: Consult physician

Other information

Store in a cool dry place with lid closed tightly

Inactive ingredients

Aloe Barbadensis Leaf Extract, Arctium Lappa Root (Burdock) Extract, Arnica Montana Flower Extract, Boswellia Carterii Resin Extract, Calendula Officinalis Extract, Camellia Sinensis Leaf Extract, Camphor, Carbomer, FD&C Blue #1, FD&C Yellow #5, Glycerin, Ilex Paraguariensis (Mate) Leaf Extract, Isopropyl Alcohol, Isopropyl Myristate, Melissa Officinalis (Lemon Balm) Leaf Extract, Silica, Tocopheryl Acetate, Triethanolamine, Water.



COLD THERAPY PAIN RELIEF MEIJER

menthol 4% gel

Product Information Product Type HUMAN OTC DRUG Item Code (Source) NDC:41250-787 Route of Administration TOPICAL

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
Menthol (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	Menthol	4 g in 100 g		

Inactive Ingredients	
Ingredient Name	Strength
ALOE VERA LEAF (UNII: ZY8 1Z8 3H0 X)	

ARCTIUM LAPPA ROOT (UNII: 597E9BI3Z3)	
ARNICA MONTANA FLOWER (UNII: OZ0E5Y15PZ)	
FRANKINCENSE (UNII: R9 XLF1R1WM)	
CALENDULA OFFICINALIS FLOWER (UNII: P0M7O4Y7YD)	
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	
CAMPHOR (SYNTHETIC) (UNII: 5TJD82A1ET)	
CARBOMER HOMOPOLYMER TYPE C (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNI: 4Q93RCW27E)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
Glycerin (UNII: PDC6A3C0OX)	
ILEX PARAGUARIENSIS LEAF (UNII: 1Q953B4O4F)	
Isopropyl Alcohol (UNII: ND2M416302)	
Isopropyl Myristate (UNII: 0 RE8 K4LNJS)	
MELISSA OFFICINALIS LEAF (UNII: 50 D2ZE9 219)	
SILICON DIO XIDE (UNII: ETJ7Z6 XBU4)	
.ALPHATO COPHEROL ACETATE (UNII: 9E8X80D2L0)	
TROLAMINE (UNII: 9O3K93S3TK)	
Water (UNII: 059QF0KO0R)	

Packaging				
# Item Code Package Description		Marketing Start Date	Marketing End Date	
ı	1 NDC:41250-787-03 85 g in 1 TUBE; Type 0: Not a Combination Product		07/11/2018	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	07/11/2018	

Labeler - Meijer (006959555)

Registrant - Product Quest Mfg (927768135)

Establishment			
Name	Address	ID/FEI	Business Operations
Product Quest Mfg		927768135	manufacture(41250-787), label(41250-787)

Revised: 7/2018 Meijer