BERRI-FREEZ- menthol gel
Geritrex 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.

Berri-Freez

Drug Facts

Active Ingredient Purpose

Menthol USP 4.5% Pain Relieving Gel

Uses

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

Directions

For adults or children 2 years of age and older

Children under 2 years of age, consult a doctor

Cleanse and dry skin

Apply to affected area not more than 3 to 4 times daily

May be used with wet or dry bandages in conjunction with ice packs

Keep container tightly closed

Apply to affected area not more than 3 to 4 times daily

Warnings

For External Use Only Use only as directed

Avoid contact with the eyes. Do not bandage tightly

Do not apply to wounds or damaged skin

Do not use with a heating pad

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

Inactive Ingredients

Camphor, Carbomer 940, FD&C Blue#1, FD&C Yellow#5

DMDM Hydantoin, Glycerine, I.paraguariensis Extract, Isopropyl Alcohol

Methyl & Propyle paraben, Silicon Dioxide, Thyme, Triethanolamine, water

Keep away from heat and open flame

Store at room temperature 15°-30°C (59°-86°F)

Keep out of reach of children if swallowed, get medical attention or contact the poison control center immediately

BERRI-FREEZ

menthol gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:54162-009
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	5.085 g in 113 g

Inactive Ingredients	
Ingredient Name	**Strength**
CAMPHOR (SYNTHETIC) (UNII: 5TJD82A1ET)	
CARBOMER 940 (UNII: 4Q93RCW27E)	

FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
DMDM HYDANTOIN (UNII: BYR0546TOW)	
GLYCERIN (UNII: PDC6A3C0OX)	
ILEX PARAGUARIENSIS LEAF (UNII: 1Q953B4O4F)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
THYME (UNII: CW657OBU4N)	
TROLAMINE (UNII: 9O3K93S3TK)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54162-009-04	113 g in 1 TUBE; Type 0: Not a Combination Product	07/31/2015	
2	NDC:54162-009-16	454 g in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	07/31/2015	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	07/31/2015	

Labeler - Geritrex LLC (112796248)

Registrant - Geritrex LLC (112796248)

Establishment

Name	Address	ID/FEI	Business Operations
Geritrex LLC		112796248	manufacture(54162-009)

Revised: 10/2016 Geritrex LLC