BRAZILIAN MENTHOL PAIN RELIEVING- menthol cream
DDR Product, LLC

BRAZILIAN MENTHOL Pain Relieving

DRUG FACTS:

Active Ingredient:

Menthol 10.00%

Topical Analgesic

Indications:

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

Warnings:

- For external use only.
- Avoid contact with eyes.
- If symptoms persist for more than seven days, discontinue use and consult physician.

Keep out of reach of children.

- If swallowed, consult physician.
- Do not apply to wounds or damaged skin.
- Do not bandage tightly.

If pregnant or breast feeding,

contact physician prior to use.

Directions:

- Adults and children two-years of age or older: Apply to affected area not more than three to four times daily.
- Children under two-years of age: consult a physician.

Additional Information:

Store at room temperature.

Other Ingredients:

Aloe Barbadensis Leaf (Aloe Vera Gel) Juice, Aqua (Deionized Water), Arnica Montana Extract, Ascorbic Acid (Vitamin C), Boswellia Serrata Extract, Cetearyl Olivate, Ethylhexylglycerin, Glycerin, Glyceryl Stearate, Helianthus Annuus (Sunflower) Oil, Magnesium Sulfate, Methylsulfonylmethane (MSM), Phenoxyethanol, SD-Alcohol 40B, Sorbitan Olivate, Tocopheryl Acetate (Vitamin E), Xanthan Gum, Zemea (Corn) Propanediol.

Package Labeling:

BRAZILIAN MENTHOL PAIN RELIEVING

menthol cream

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:71977-126
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	100 mg in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
WATER (UNII: 059QF0KO0R)	
ARNICA MONTANA (UNII: O80TY208ZW)	
ASCORBIC ACID (UNII: PQ6CK8PD0R)	
INDIAN FRANKINCENSE (UNII: 4PW41QCO2M)	
CETEARYL OLIVATE (UNII: 58B69Q84JO)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
GLYCERIN (UNII: PDC6A3C0OX)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
HELIANTHUS ANNUUS FLOWERING TOP (UNII: BKJ0J3D1BP)	
MAGNESIUM SULFATE, UNSPECIFIED FORM (UNII: DE08037SAB)	
DIMETHYL SULFONE (UNII: 9H4PO4Z4FT)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
SORBITAN OLIVATE (UNII: MDL271E3GR)	
.ALPHA.-TOCOPHEROL (UNII: H4N855PNZ1)	

XANTHAN GUM (UNII: TTV12P4NEE)	
CORN (UNII: 0N8672707O)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71977-126-04	1 in 1 BOX	12/27/2017	
1		118.294 mL in 1 JAR; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M017	12/27/2017	

Labeler - DDR Product, LLC (080781689)

Establishment

Name	Address	ID/FEI	Business Operations
Pure Source, LLC		080354456	manufacture(71977-126)

Revised: 11/2023 DDR Product, LLC