BRAZILIAN MENTHOL PAIN RELIEVING ROLL ON- menthol cream
DDR Product, LLC

BRAZILIAN MENTHOL Pain Relieving Roll-On

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:

Ingredients: Aloe Barbadensis Leaf (Aloe Vera Gel) Juice, Aqua (Deionized Water), Arnica Montana Extract, Ascorbic Acid (Vitamin C), Boswellia Serrata Extract, Carbomer, Magnesium Sulfate, Methylisothiazolinone, Methylsulfonylmethane (MSM), Polysorbate-20, SD-Alcohol 40B, Triethanolamine.

Package Labeling:

BRAZILIAN MENTHOL PAIN RELIEVING ROLL ON

menthol cream

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:71977-125
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)	
CARBOXYPOLYMETHYLENE (UNII: 0A5MM307FC)	
MAGNESIUM SULFATE, UNSPECIFIED FORM (UNII: DE08037SAB)	
METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA)	
DIMETHYL SULFONE (UNII: 9H4PO4Z4FT)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
TROLAMINE (UNII: 9O3K93S3TK)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71977-125-04	88.72 mL in 1 BOTTLE; Type 0: Not a Combination Product	12/27/2017	

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)

Revised: 11/2023 DDR Product, LLC