ARTHRIPAIN RELIEF - menthol cream NDI Solutions 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.

Drug Facts

Use Temporarily relieves minor aches and pains of muscles and joints associated with:

- simple backache
- arthritis
- strains
- bruises
- sprains

Warnings

For external use only

Do not use

on wounds or damaged skin

When using this product

- avoid contact with eyes or mucous membranes
- do not bandage tightly

Stop use and ask a doctor if

- condition worsens or symptoms persist for more than 7 days
- symptoms clear up and occur again within a few days

Keep out of reach of children

Directions

- Adult and children 2 years of age and older: Apply to affected area not more than 3 to 4 times daily.
- Children under 2 years of age: Consult a physician.

Inactive Ingredients: aloe vera gel, cetyl alcohol, cetyl esters (proprietary blend of esterfied fatty acids)(7.5%), cinnamon oil, eucalyptus oil, glyceryl stearate, grape seed oil, hypromellose, jojoba oil, peppermint oil, potassium sorbate, purified water, squalane, stearic acid, stearyl alcohol, tea tree oil, vegetable glycerin, wintergreen oil.

ArthriPain packaging

eucalyptus oil, glyceryl stearate, grape seed oil, hypromellose, jojoba oil, peppermint oil, potassium sorbate, purified water, squalane, stearic

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acid, stearyl alcohol, tea tree oil, vegetable glycerin, wintergreen oil.

NORTH STAR

ArthriPain Relief Cream

Provides Penetrating Joint Pain Relief

Paraben-Free!

Net Wt. 2 oz (57g)

ARTHRIPAIN RELIEF

menthol cream

Product Information

HUMAN OTC DRUG NDC:50972-278 Product Type Item Code (Source)

Purpose

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Menthol (UNII: L7T10EIP3A) (Menthol - UNII:L7T10EIP3A)	Menthol	12.5 mg in 1 g

Inactive Ingredients Ingredient Name Strength Aloe Vera Leaf (UNII: ZY81Z83H0X) Cetyl Alcohol (UNII: 936JST6JCN) Cetyl Esters Wax (UNII: D072FFP9GU) Cinnamon Oil (UNII: E5GY4I6YCZ) EUCALYPTUS OIL (UNII: 2R04ONI662) GLYCERYL MONOSTEARATE (UNII: 230 OU9 XXE4) GRAPE SEED OIL (UNII: 930MLC8XGG) HYPROMELLOSE (UNII: 3NXW29V3WO) JOJOBA OIL (UNII: 724GKU717M)

PEPPERMINT OIL (UNII: AV092KU4JH)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
WATER (UNII: 059QF0KO0R)	
SQUALANE (UNII: GW89575KF9)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
STEARYL ALCOHOL (UNII: 2KR89I4H1Y)	
TEA TREE OIL (UNII: VIF565UC2G)	
GLYCERIN (UNII: PDC6A3C0OX)	
METHYL SALICYLATE (UNII: LAV5U5022Y)	

Packaging			
# Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC:50972-278-01	57 g in 1 TUBE		

Marketing Information					
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
OTC monograph not final	part348	07/01/2010			

Labeler - NDI Solutions LLC (828825989)

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