ARNEU - camphor menthol cream CC Medical Devices Inc

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 Ingredients

Camphor 3.100%

Menthol 3.000%

Purpose

Topical Analgesic

Topical Analgesic

Uses

For the temporary relief of minor aches and pains of muscles and joints.

Penetrating pain relief.

Warnings

For external use only.

Do not bandage tightly.

Do not apply heat to the area of application.

Do not apply to open wounds or damaged skin.

Avoid contact with eyes or mucous membranes.

Ask a doctor before use, if you have ever experienced a reaction due to ingredients listed.

Stop use and consult a licensed health professional if conditions worsens or if symptoms persists for more than 7 days, or clears up and occurs again.

If pregnant or breast feeding, ask the health professional before use.

Keep out of reach of children.

If ingestion occurs, get medical help or contact a Poison Control Center right away.

Directions

Adults and children 12 years of age or older

Apply to surface, leaving a thin visible film; by applying a thicker film, the intensity is increased.

Apply to the area of pain, extending outside of the area slightly.

Apply 2 times a day minimum (do not exceed application of 4 times daily).

Allow to dry completely before applying loose clothing over the area.

Directions

(Children 12 years of age or younger)

Ask your doctor or a licensed health professional.

Other Information

Store at 15-30 C (50-85 F). Keep sealed tightly.

No triethanolamine used in manufacturing.

Have all medical diagnosis confirmed by a healthcare professional before treating.

Do not use if cap seal has been tampered with.

Inactive Ingredients

Water, propylene glycol, glycerin, witch hazel, carbomer, sodium hydroxymethylglycinate, fragrance, arnica montana flower extract, potassium asparate, sodium chlorite, willow bark extract, green tea leaf extract, sodium hydroxide, spirulina maxima extract, aloe vera leaf juice, ginger root extract, bromelain, boswellia serrata gum, sodium sesquicarbonate, sodium bicarbonate, capsaicin (capsicum frutescens fruit extract).

ArNeu

penetrating pain relief

God Formula

Topical Analgesic Counterirritant

For the Temporary Relief of Minor Aches and Pains of Muscles and Joints

NET WT. 3.0 OZ. (85 g.)

www.arneu.com

NDC 42046-002-03

US Pat.7,704,522 and Pat. Pending

Made in USA

ARNEU

camphor menthol cream

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:42046-002
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
Camphor (Natural) (UNII: N20HL7Q941) (Camphor (Natural) - UNII:N20HL7Q941)	Camphor (Natural)	3.1 g in 100 g		
Menthol (UNII: L7T10EIP3A) (Alcohol - UNII:3K9958V90M)	Menthol	3.0 g in 100 g		

Ingredient Name Water (UNII: 059QF0KO0R) Propylene Glycol (UNII: 6DC9Q167V3) Glycerin (UNII: PDC6A3C0OX)	Strength	
Propylene Glycol (UNII: 6DC9Q167V3)		
Glycerin (UNII: PDC6A3C0OX)		
Witch Hazel (UNII: 10 114J0 U34)		
Arnica Montana Flower (UNII: OZ0E5Y15PZ)		
Potassium Aspartate (UNII: OC4598NZEQ)		
Sodium Chlorite (UNII: G538EBV4VF)		
Willow Bark (UNII: S883J9JDYX)		
Green Tea Leaf (UNII: W2ZU1RY8B0)		
Sodium Hydroxide (UNII: 55X04QC32I)		
Aloe Vera Leaf (UNII: ZY8 1Z8 3H0 X)		
Ginger (UNII: C5529G5JPQ)		
Bromelains (UNII: U182GP2CF3)		
Sodium Bicarbonate (UNII: 8MDF5V39QO)		
Capsaicin (UNII: S07O44R1ZM)		

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:42046-002-03	85 g in 1 JAR		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	08/28/2010	

Labeler - CC Medical Devices Inc (121825868)

Establishment

Name	Address	ID/FEI	Business Operations
Gar Laboratories		074933615	manufacture

Revised: 8/2010 CC Medical Devices Inc