

AVEDANA COOL HOT ICE- menthol gel

Unipack, 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.

Active Ingredient

Active Ingredients	Purpose
Menthol 2%.....	External Pain Reliever

Purpose

External Pain Reliever

Uses

Temporarily relief of minor pains of muscles and joints associated with - simple back ache - arthritis - sprains, strains, or bruises

Warnings

Warnings

For external use only. Avoid contact with eyes

Do not use

Do not use - internally - with heating pad or devices - on wounds or damaged skin

Ask a doctor before use

Ask doctor before use if you have sensitive skin

When using this product

When using this product - Use only as directed - do not bandage tightly - avoid contact with eyes and mucus membranes

If pregnant or breast-feeding

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

Keep out of reach of children

Keep out of reach of children. In case of accidental ingestion, get medical help or contact a Poison Control Center immediately.

Directions

-Adult and children 2 years of age and older. Clean skin thoroughly. Apply liberally to affected area no more than 3-4 times daily. No protective cover needed.

- May be used with ice packs
- May be used with wet or dry bandages, but wrap loosely
- Children under 2 years of age, consult a doctor

Other information

Other information store between 59^o - 86^oF (15^o - 30^oC)

Keep tightly closed

Do not use, pour, spill, or store near heat or open flame

Other ingredients

Camphor, Carbomer 940, FDC Blue #1, Isopropyl alcohol, Propylene glycol, Purified water, Sodium hydroxide

Product Label



AVEDANA COOL HOT ICE			
menthol gel			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:43749-321

Route of Administration

TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	2 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
CAMPHOR (SYNTHETIC) (UNII: 5TJD82A1ET)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
CARBOMER HOMO POLYMER TYPE C (UNII: 4Q93RCW27E)	
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)	
WATER (UNII: 059QF0K00R)	

Product Characteristics

Color	blue	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:43749-321-08	227 g in 1 JAR; Type 0: Not a Combination Product	11/04/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	11/04/2017	

Labeler - Unipack, Inc. (009248480)**Establishment**

Name	Address	ID/FEI	Business Operations
Unipack, Inc.		009248480	manufacture(43749-321)

Revised: 5/2018

Unipack, Inc.