AMAR ICE- menthol gel AMAR REMEDIES LIMITED

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.

Amar ICE GEL

Drug Facts

Active Ingredient

Menthol 2.5%

Purpose

Topical analgesic

Uses

- temporarily relieves minor aches and pains of muscles and joints associated with:
 - arthritis
 - bruises
 - simple backache
 - sport injuries
 - strains
 - sprains
- provides cooling penetrating relief

Warnings

For external use only

Do not use

• with heating pads or heating devices

When using this product

- do not use in or near the eyes
- do not apply to wounds or damaged skin
- do not bandage tightly

Stop use and ask a doctor if

- condition worsens
- symptoms last more than 7 days or clear up and occur again within a few days
- redness or irritation develops

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

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- clean affected area before applying product
- adults 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: ask a doctor

Other information

- store in a cool place
- keep lid tightly closed
- do not use, pour, spill or store near heat or open flame

Inactive ingredients

Water, Camphor, Carbopol, Methyl Paraben Sodium, Propyl Paraben Sodium, Wintergreen oil, Propylene Glycol, Phenoxy ethanol, ISO Propyl alcohol, Sodium Hydroxide, Cl 42090.

PRINCIPAL DISPLAY PANEL - 227 g Jar Label

Amar

ICE GEL

Net Wt 8 oz (227g)



AMAR ICE

menthol gel

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:41499-123	
Route of Administration	TOPICAL			

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
Menthol (UNII: L7T10EIP3A) (Menthol - UNII:L7T10EIP3A)	Menthol	2.5 g in 100 g		

Inactive Ingredients			
Ingredient Name	Strength		
Camphor (Synthetic) (UNII: 5TJD82A1ET)	0.7 g in 100 g		
MethylParaben Sodium (UNII: CR6K9C2NHK)			

Product Characteristics			
Color	BLUE	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging			
# Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC:41499-123-01	227 g in 1 JAR		

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph final	part341	05/01/2010		

Labeler - AMAR REMEDIES LIMIT ED (677141751)

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