MIRACLE ICE ULTRA STRENGTH- menthol and camphor (synthetic) gel FDN Enterprises,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.

Miracle Ice Ultra Strength

Drug Facts

Active Ingredient	Purpose
Menthol 1%	Topical analgesic
Camphor 0.5%	Topical analgesic

Uses

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

Warnings

For external use only

Do not use

- with other topical pain relievers
- 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 at room temperature 59°-86°F (15°-30°C).
- Keep jar tightly closed and away from open heat or flame

Inactive ingredients

Aqua, Propylene Glycol, Carbomer, Methyl Salicylate, Sodium Hydroxide, Sodium Methyl Paraben, Sodium Propyle Paraben, CI 14720, CI 16185, CI 42090

Distributed by: FDN Enterprises, LLC. Opa Locka, FL 33054

PRINCIPAL DISPLAY PANEL - 227 g Jar Label

FDN Medical® MIRACLE **ICE**

ULTRA STRENGTH

ANALGESIC GEL NET WT. 8 OZ (227 g)



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Uses • temporarily relieves minor aches and pains of muscles and joints associated with: • arthritis • simple backache • strains • bruises • sport injuries • sprains • bruises • sport injuries • sprains Varnings: For external use only No not use • with other topical pain relievers • with heating pads * Theating devices When using this product • do not use in or near the eyes • do no puply to wounds or damaged skin • do not bandage tightly top use and ask a doctor if • condition worsens • symptoms has note than 7 days or clear up and occur again within a few days redness or irritation develops redness or irritation develops redness or irritation develops redness or irritation develops Poison Control Center right away. Mections • clean affected area before applying product • adults an and 10 of times daily, children under 2 years of age; ask a doctor Nher information • Store at room temperature 59:88 F (15-30°C). Reep jar tightly closed and away from open heat or flame Inactive ingredients: Aqua, Propylene Glycol, Carbomer, Methy Salicylate, Sodium Pydroxide, Sodium Pydroxide, Sodium Propyles
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Paraben, CI 14720, CI 16185, CI 42090
Información sobre este producto
Ingrediente activo Propósito Menthol 1%Analgésico tópico Alcarlor 0.5%Analdésico tópico
oara el alivio temporal de dolores y malestares menor s y articulaciones relacionados con: • artritis • dolor imple • esguinces • Contusiones • lesiones deportivas • lor
Advertencia: Uso externo solamente.
No usar Con almohadilias eléctricas o calentadores.
Al usar este producto • No usar en o airededor de los ojos. • No aplicar sobre heridas o piel abierta. • No apretar los vendajes.
Dejar de usar y consultar a un médico si » la condición empeora • los sintomas duran más de 7 días o, después de aliviarse, vuelven a los pocos días » se produce inflación o enrojecimiento.
Mujeres embarazadas o lactando, consultar con un especialista de salud antes de usar este producto.
Mantener alejado de los niños. De ser ingerido, procurar de inmediato asistencia médica o contactar a un centro de control toxicológico.
Modo de uso • Desinfectar el área afectada antes de aplicar este producto. • Adultos y niños mayores de 2 años: aplicar sobre el área afectada no más de 3 a 4 veces al día. • Niños menoses de 2 años de ectad; consultar con un médico.
Información adicional e guardar a temperatura ambiente '59°-86°-F (15°-30°C). • mantener el envase cerrado herméticamente y alejado de fuentes de calor o las llamas.
Excipientes: Agua, propilenglicol, carbómero, salicilato de metilo, hidróxido de sodio, metilparabeno sódico, propiliparabeno sódico, CI 14720, CI 16185, CI 42090

MIRACLE ICE ULTRA STRENGTH

menthol and camphor (synthetic) gel

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:60691-116
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
Menthol (UNII: L7T10EIP3A) (Menthol - UNII:L7T10EIP3A)	Menthol	1 g in 100 g	
Camphor (synthetic) (UNII: 5TJD82A1ET) (Camphor (synthetic) - UNII:5TJD82A1ET)	Camphor (synthetic)	0.5 g in 100 g	

Inactive Ingredients	
Ingredient Name	Strength
Water (UNII: 059QF0KO0R)	
Propylene Glycol (UNII: 6DC9Q167V3)	

Methyl Salicylate (UNII: LAV5U5022Y)	
Sodium Hydroxide (UNII: 55X04QC32I)	
Methylparaben Sodium (UNII: CR6K9C2NHK)	
Propylparaben Sodium (UNII: 625NNB0G9N)	
Carmoisine (UNII: DR4641L47F)	
Amaranth (UNII: 37RBV3X49K)	
FD&C Blue No. 1 (UNII: H3R47K3TBD)	

F	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:60691-116-30	227 g in 1 JAR			

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part348	07/15/2013	

Labeler - FDN Enterprises,LLC (965743867)

Revised: 9/2013 FDN Enterprises,LLC