

ICE EXTERNAL ANALGESIC LEADER- menthol gel

Cardinal Health

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

Menthol 2.0%

Uses

For the temporary relief of minor aches and pains of muscles and joints associated with: simple backache, arthritis, strains, bruises, and sprains.

Warnings

For external use only. When using this product: avoid contact with the eyes, do not bandage tightly, do not apply to wounds or damaged skin, and do not use with heating pads or other heating devices. **Stop use and ask doctor if:** condition gets worse, symptoms last more than 7 days, or symptoms clear up and occur again in a few days.

Directions

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: do not use, consult a doctor.

Inactive ingredients

Aloe Barbados Leaf Juice, SD Alcohol 40, Propylene Glycol, Glycerin, Simethicone, Tocopheryl Acetate, Triethanolamine, Carbomer, Diazolidinyl Urea, Methylparaben, Propylparaben, Disodium Cocoamphodipropionate, Disodium EDTA.

Purpose

Pain relieving gel.

Keep out of reach of children.

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

Ice Gel External Analgesic.

NDC 37205-616-34

LEADER®

THERAPEUTIC Ice Gel

External Analgesic

Minor Muscle & Joint Aches
Strains, Sprains, And Bruises
Backache And Arthritis

NET WT. 8 OZ (227 g)

***Compare to Mineral Ice® active ingredient**

SATISFACTORY GUARANTEE

Drug Facts	Purpose Menthol 2.0%.....Pain relieving gel
Active ingredient Menthol 2.0%.....Pain relieving gel	Uses for the temporary relief of minor aches and pains of muscles and joints associated with: • simple backache • arthritis • strains • bruises • sprains
Warnings For external use only When using this product: • do not bandage tightly • do not apply to wounds or damaged skin • do not use with heating pads or other heating devices Stop use and ask doctor if: • condition worsens, or if symptoms persist for more than 7 days or clear up and occur again within a few days Keep out of the reach of children. If swallowed get medical help or contact a Poison Control Center.	Directions • 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: do not use, consult a doctor
Inactive ingredients Aloe Barbadensis Leaf Juice, SD Alcohol 40, Propylene Glycol, Glycerin, Simethicone, Tocopheryl Acetate, Triethanolamine, Carbomer, Diazolidinyl Urea, Methylparaben, Propylparaben, Disodium Cocoamphodipropionate, Disodium EDTA.	*This product is not manufactured by Bristol-Myers Products, owner of the registered trademark, Mineral Ice®.

All Leader® Brand products are 100% satisfaction guaranteed or return to place of purchase for a full refund.

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ICE EXTERNAL ANALGESIC LEADER

menthol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:37205-616
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Menthol (UNII: L7T10EIP3A) (Menthol - UNII:L7T10EIP3A)	Menthol	.02 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
Ammonia (UNII: 5138Q19F1X)	
Carbomer 934 (UNII: Z135WT9208)	
Cupric Sulfate (UNII: LRX7AJ16DT)	
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)	
Isopropyl Alcohol (UNII: ND2M416302)	
Magnesium Sulfate (UNII: DE08037SAB)	
Sodium Hydroxide (UNII: 55X04QC32I)	
Thymol (UNII: 3J50XA376E)	
Water (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:37205-616-34	227 g in 1 JAR		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part348	12/01/2011	

Labeler - Cardinal Health (097537435)

Revised: 1/2011

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