

PAIN RELIEVING- 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.

Pain Relieving Gel

Drug Facts

Active Ingredients

Active Ingredients
Menthol 3.5%

Purpose

Cooling Pain Relief

Uses

Temporary relief from minor aches and pains of sore muscles and joints associated with

- arthritis
- backache
- strains
- sprains

Warnings:

For external use only

Ask a doctor before use if you have:

sensitive skin, are pregnant or breast feeding

When Using This Product:

- Avoid contact with eyes or mucous membranes
- Do not apply to wounds, damaged or irritated skin, or if excessive irritation develops
- Do not bandage or use with heating pad or device. ointments, creams, sprays, liniments
- Wash hands after with cool water

Stop Use And Ask A Doctor If:

Condition worsens. symptoms persist more than 7 days, or clear up and recur

Keep out of reach of children:

If ingested, get medical help. Contact Poison Control Center immediately.

Directions:

- Adults / Children 2 years and older: Massage onto affected area up to 4 times daily.
- Children under 2 years of age: Consult physician

Other Information:

Store in cool dry place, lid closed tightly. keep away from excessive heat or open flame.

Inactive Ingredients:

Water, isopropyl alcohol, herbal extract (*Ilex paraguariensis*), menthol, carbomer, triethanolamine, silicon dioxide, methylparaben, glycerine, propylene glycol, FDandC blue #1

Package Labeling:

NDC 37205-824-26



EXTRA STRENGTH

Pain Relieving Gel

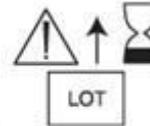
Provides Hours of Long Lasting Relief from:

Arthritis - Backache
Sore Muscles - Stiff Joints

Fast Acting
Greaseless
Vanishing Scent



4 FL OZ (118 mL)



LOT

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Menthol 3.5%	Cooling Pain Relief
Uses	
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Warnings:	
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Ask a doctor before use if you have:	
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When Using This Product:	
<ul style="list-style-type: none"> • Avoid contact with eyes or mucous membranes • Do not apply to wounds, damaged or irritated skin, or if excessive irritation develops • Do not bandage or use with heating pad or device, ointments, creams, sprays, liniments • Wash hands after with cool water 	
Stop Use And Ask A Doctor If: Condition worsens, symptoms persist more than 7 days, or clear up and recur	
Keep out of reach of children: If ingested, get medical help. Contact Poison Control Center immediately.	
Directions:	
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Inactive Ingredients: water, isopropyl alcohol, herbal extract (Ilex paraguariensis), menthol, carbomer, triethanolamine, silicon dioxide, methylparaben, glycerine, propylene glycol, FD&C blue #1	
All Leader® Brand products are 100% satisfaction guaranteed or return to place of purchase for a full refund.	

Distributed By: Cardinal Health, Dublin, OH 43017
www.myleader.com CIN 3999521

PAIN RELIEVING

menthol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:37205-824
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A) (MENTHOL, UNSPECIFIED FORM - UNII:L7T10EIP3A)	MENTHOL, UNSPECIFIED FORM	35 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
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WATER (UNII: 059QF0KO0R)
ISOPROPYL ALCOHOL (UNII: ND2M416302)
TROLAMINE (UNII: 903K93S3TK)
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)
METHYLPARABEN (UNII: A2I8C7HI9T)
GLYCERIN (UNII: PDC6A3C0OX)
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:37205-824-26	1 in 1 CARTON	01/18/2012	12/31/2024
1		118 mL in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	01/18/2012	12/31/2024

Labeler - Cardinal Health (097537435)

Establishment

Name	Address	ID/FEI	Business Operations
Span Packaging Services LLC		117101131	manufacture(37205-824)

Establishment

Name	Address	ID/FEI	Business Operations
Span Packaging Services LLC		557434805	manufacture(37205-824)

Revised: 12/2021

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