COLD THERAPY PAIN RELIEF 360 MEIJER- menthol 10.5% spray Meijer

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

Uses Temporary relief from minor aches and pains of sore muscles and joints associated with arthritis, backache, strains and sprains

Warnings

For external use only.

Flammable: Do not use while smoking or near heat or flame. **When using this product** • avoid contact with the eyes or mucous membranes • do not apply to wounds or damaged skin • do not apply to the irritated skin • do not bandage • wash hands after use with cool water • do not use with heating pad or device **Stop use and ask a doctor if** • condition worsens, or if symptoms persist for more than 7 days, or clear up and reoccur.

Keep out of reach of children. If accidentally ingested get medical help or contact a Poison Control Center immediately

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: Consult physician.

Inactive ingredients Alcohol Denat., Arnica Montana Flower Extract, Calendula Officinalis Flower Extract, Camellia Sinensis Leaf Extract, Chamomile Recutita Flower Extract, Dimethyl Sulfone, Echinacea Angustifolia Extract, Ilex Paraguariensis Leaf Extract, Isopropyl Myristate, Juniperus Communis Fruit Extract, Water

Drug Facts

Active ingredient

Purpose

Menthol 10.5%......

.Topical Analgesic

Uses Temporary relief of minor aches and pains of muscles and joints associated with arthritis, simple backache, strains and sprains.

Warnings

For external use only.

Flammable: Do not use while smoking or near heat or flame.

When using this product • avoid contact with the eyes or mucous membranes • do not apply to wounds or damaged skin • do not apply to the irritated skin or if excessive irritation develops • do not bandage • do not use with heating pad or device

Stop use and ask a doctor if • condition worsens, or if symptoms persist for more than 7 days, or clear up and occur again within a few days.

If pregnant or breastfeeding ask a health professional before use.

Keep out of reach of children. If accidentally ingested get medical help or contact a Poison Control Center immediately.

Directions • Adults and children 12 years of age and older:
Spray on to the affected areas not more than 3-4 times daily.
• Children under 12 years of age: Consult physician.

Other information Store in a cool dry place with lid closed tightly

Inactive ingredients Alcohol Denat., Amica Montana Flower Extract, Calendula Officinalis Flower Extract, Camellia Sinensis Leaf Extract, Chamomile Recutita Flower Extract, Dimethyl Sulfone, Echinacea Angustifolia Extract, Ilex Paraguariensis Leaf Extract, Isopropyl Myristate, Juniperus Communis Fruit Extract, Water.

Questions? 866-483-2846

*This product is not manufactured or distributed by Hygenic Intangible Property Holding Co., owner of the registered trademark Biofreeze®.

DIST. BY MEIJER DISTRIBUTION, INC. GRAND RAPIDS, MI 49544







NDC 41250-789-03

Compare to

Biofreeze®
active ingredient*

pain relief 360° spray

TOPICAL ANALGESIC

Cooling Pain Relief Menthol 10.5%

For Temporary Relief of Minor Aches and Pains of Muscles and Joints

Vanishing Scent Sprays at any Angle Paraben Free

NET WT 3 OZ (85 g)

COLD THERAPY PAIN RELIEF 360 MEIJER

menthol 10.5% spray

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:41250-789

Route of Administration TOPICAL

Active Ingredient/Active Moiety

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Ingredient Name	Basis of Strength	Strength
Menthol (UNII: L.7T10EIP3A) (MENTHOL - UNII:L.7T10EIP3A)	Menthol	10.5 g in 100 g

Inactive Ingredients		
Ingredient Name	Strength	
Alcohol (UNII: 3K9958V90M)		
ARNICA MONTANA FLOWER (UNII: OZ0E5Y15PZ)		

CALENDULA OFFICINALIS FLOWER (UNII: P0M7O4Y7YD)	
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	
CHAMO MILE (UNII: FGL3685T2X)	
Dimethyl Sulfone (UNII: 9H4PO4Z4FT)	
ECHINACEA ANGUSTIFOLIA (UNII: VB06AV5US8)	
ILEX PARAGUARIENSIS LEAF (UNII: 1Q953B4O4F)	
Isopropyl Myristate (UNII: 0 RE8 K4LNJS)	
JUNIPER BERRY (UNII: O84B5194RL)	
Water (UNII: 059QF0KO0R)	

P	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:41250-789-03	85 g in 1 CAN; Type 0: Not a Combination Product	07/11/2018	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	07/11/2018	

Labeler - Meijer (006959555)

Registrant - Product Quest Mfg. (927768135)

Establishment				
Name	Address	ID/FEI	Business Operations	
Product Quest Mfg.		927768135	manufacture(41250-789), label(41250-789)	

Revised: 7/2018 Meijer