

COLD THERAPY PAIN RELIEF MEDICATED GNP- menthol spray

Amerisource Bergen

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.

Cold Therapy Pain Relief Medicated Spray [GNP]

Active ingredient

Purpose

Menthol 10.5% Topical Analgesic

Uses

Temporary relief from minor aches and pains of muscles and joints associated with arthrttis, simple backache, strains and sprains

Warnings

For external use only.

Flammable: Do not use while smoo~ng 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 again within a few days.

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, EchinaceaAngustifolia Extract, Ilex Paraguariensis Leaf Extract, Isopropyl Myristate, Juniperus Communis Fruit Extract, Water

Questions?

888-793-8450



*Compare to
active ingredients
in Biofreeze®

NDC 46122-657-21

Cold Therapy

PAIN RELIEF MEDICATED SPRAY

**MENTHOL 10.5
TOPICAL ANALGESIC**

Soothing Relief Therapy for:

- Arthritis
- Sore Muscles
- and Joint Discomfort

Non-Greasy
Quick Drying

NET WT. 3 fl oz
(85 g)

Drug Facts

Active ingredient

Menthol 10.5%.....Topical Analgesic

Purpose

Uses Temporary relief from 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 • 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 again within a few days.

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

Questions? 888-793-8450

*This product is not manufactured or distributed by Biofreeze®.



Distributed By
AmerisourceBergen
1300 Morris Drive
Chesterbrook, PA 19087
Questions or Concerns?
www.mygnp.com

ABC# 10236985



COLD THERAPY PAIN RELIEF MEDICATED GNP

menthol spray

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:46122-657
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	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)	
CHAMOMILE (UNII: FGL3685T2X)	
DIMETHYL SULFONE (UNII: 9H4PO4Z4FT)	
ECHINACEA ANGUSTIFOLIA WHOLE (UNII: VB06AV5US8)	
ILEX PARAGUARIENSIS LEAF (UNII: 1Q953B4O4F)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
JUNIPER BERRY (UNII: O84B5194RL)	
WATER BUFFALO (UNII: 0A4PW6CRAI)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:46122-657-21	85 g in 1 CAN; Type 0: Not a Combination Product	01/12/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	01/12/2021	

Labeler - Amerisource Bergen (007914906)

Registrant - Inspec Solutions LLC (081030372)

Establishment

Name	Address	ID/FEI	Business Operations
Inspec Solutions LLC		081030372	manufacture(46122-657)