

BERRI-FREEZ- menthol spray

Geritrex 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.

Berri-Freez

Active Ingredient:

Menthol USP 10%

Purpose:

Cooling Pain Reliever

Uses:

Temporary relief of minor aches and pains related to:

- Back, Shoulder, and Neck strains
- Ankle, Knee, Hip and Elbow joint discomfort
- Muscle sprains and strains
- Arthritis

Warnings:

For external use only. Keep out of reach of children.

Flammable: Keep away from excessive heat or open flame. If accidentally ingested, get medical help or contact a Poison Control Center immediately.

When using this Product:

Avoid contact with the eyes or mucous membranes

Do not apply to wounds or damaged skin

Do not apply to irritated skin or if excessive irritation develops

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 or reoccur

If pregnant or breastfeeding ask a health professional before use.

Adults and children 12 years of age and older:

1-2 sprays on the affected areas as needed but not more than 4 times daily; massage not necessary.

Inactive Ingredients:

Arnica Montana, Calendula, Chamomile, Echinacea, Ethanol, ILEX Paragurenis, Isopropyl Myristate, Juniper Berry, Water, White Tea

PMS 7473

PMS 7462

54162-002-04



Berri-Freez
Pain Relieving Spray

4 FL. OZ. (118ml)

•Fast Acting •Stainless •Pleasant Herbal Scent
Compare to BIOFREEZE® by Performance Health

Drug Facts

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Geritrex Corporation
144 Kingsbridge Road East
Mount Vernon, New York 10550
1-800-736-3437
www.geritrex.com

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BERRI-FREEZ

menthol spray

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:54162-002
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	11.8 g in 118 mL

Inactive Ingredients

Ingredient Name	Strength
ARNICA MONTANA (UNII: O80TY208ZW)	
CALENDULA OFFICINALIS FLOWER (UNII: P0M7O4Y7YD)	
ECHINACEA, UNSPECIFIED (UNII: 4N9P6CC1DX)	
CHAMOMILE (UNII: FGL3685T2X)	
WHITE TEA (UNII: O0M3396E09)	
ALCOHOL (UNII: 3K9958V90M)	

ILEX PARAGUARIENSIS LEAF (UNII: 1Q953B4O4F)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
JUNIPER BERRY (UNII: O84B5194RL)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54162-002-04	118 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	07/31/2015	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	07/31/2015	

Labeler - Geritrex LLC (112796248)

Establishment

Name	Address	ID/FEI	Business Operations
Geritrex LLC		112796248	manufacture(54162-002)

Revised: 8/2016

Geritrex LLC