

HERBAL FREEZE- menthol spray
SOMBRA COSMETICS INC.

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.

Herbal Freeze Pain Relieving Gel

Active Ingredients

Menthol USP %

Purpose

Purpose
External Analgesic

Keep out of reach of children

Keep out of reach of children

Uses

Temporarily relieves minor aches and pains of muscles and joints associated with: arthritis, simple backaches, strains, bruises, and sprains

Warnings

For external use only. Do not use on wounds or damaged skin or with a heat source. **If pregnant or breastfeeding, consult a healthcare professional before use.** When using this product: avoid bandaging tightly, avoid contact with eyes, **keep out of reach of children.**

Stop use and ask doctor if: condition worsens, symptoms persist for more than 7 days, symptoms clear up and occur again within 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, rub in thoroughly until gel is absorbed, **children under 2 years of age:** consult a doctor.

Inactive Ingredients

Purified Water, Ethyl Alcohol, Arnica Montana (Arnica) Flower Extract, Populus Balsamifera (Balsam Poplar) Bud Extract, Hypericum Perforatum (St. John's Wort)

Flower Extract, Glycerin

Questions or Comments

1-877-239-4667

Spray Away the Pain
 Sore back? Sore neck?
 Muscle cramps or strain? Arthritis?
 Bruises? Is chronic soreness your
 bane? Joint aches, headaches (try a
 dab below each ear)
 Work hard. Play hard. No worries.
 Herbal Freeze is here.

Spray it on and feel it soak deep
 into your muscles. Goes on cool.
 Heats up fast. Relieves pain.
 No stain. Made with wildcrafted
 herbs. No synthetic ingredients.
 No parabens.
 All Good.

GMO FREE | GLUTEN FREE | VEGAN

 committed to responsible business

MADE IN USA | ELEMENTAL HERBS INC
 PO BOX 203 MORRO BAY CA 93443
 (877) 239-4667 | ALLGOODPRODUCTS.COM



ALL good
MAKES EVERYTHING BETTER

HERBAL FREEZE
 PAIN RELIEF ON-DEMAND
 with Arnica

ULTRA FAST ABSORPTION
 59 ML / 2 FL OZ

DRUG FACTS NDC# 61577-3385-2

Active Ingredients: Menthol, USP 6%	Purpose: External Analgesic
Uses: Temporarily relieves minor aches and pains of muscles and joints associated with: simple backaches, arthritis, strains, bruises, sprains.	
Warnings: For external use only. Do not use on open wounds or damaged skin or with a heat source. If pregnant or breastfeeding, consult a healthcare professional before use.	
When using this product: Avoid bandaging tightly, avoid contact with eyes, keep out of reach of children.	
Stop use and ask doctor if: condition worsens, symptoms persist more than 7 days, symptoms clear up and occur again within a few days.	
Directions for adults and children 2 years of age and older: spray on affected area, massage in as needed. Children under 2 years of age: consult a doctor.	
Inactive Ingredients: Water (Aqua), Ethyl Alcohol, Arnica Montana (Arnica) Flower Extract*, Populus Balsamifera (Balsam Poplar) Bud Extract*, Hypericum Perforatum (St. John's Wort) Flower Extract*, Glycerin, *Ethically wildcrafted and extracted with Organic Grain-Free Alcohol.	
Questions or comments? 1-877-239-4667	

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HERBAL FREEZE

menthol spray

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:61577-3385
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	0.06 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
ALCOHOL (UNII: 3K9958V90M)	

ARNICA MONTANA FLOWER (UNII: OZ0E5Y15PZ)	
POPULUS BALSAMIFERA LEAF BUD (UNII: 9CQ6C00G3C)	
HYPERICUM PERFORATUM FLOWER (UNII: A6V4CUE7PV)	
GLYCERIN (UNII: PDC6A3C00X)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61577-3385-3	113.4 g in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	03/08/2023	
2	NDC:61577-3385-2	85 g in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	03/08/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	03/08/2023	

Labeler - SOMBRA COSMETICS INC. (097464309)

Establishment

Name	Address	ID/FEI	Business Operations
SOMBRA COSMETICS INC.		097464309	manufacture(61577-3385) , label(61577-3385)

Revised: 3/2023

SOMBRA COSMETICS INC.