

PAIN RELIEVING- menthol gel
Safetec of America, Inc.

61010-4403-1

Drug Facts

Active Ingredient

Menthol USP 4%

Purpose

Cooling Pain Relief

Use

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

Warnings

- **For external use only.**

Flammable:Keep away from excessive heat or open flame.

Ask a doctor before use if you have:sensitive skin.

When using this product:

- Avoid contact with eyes or mucous membranes
- Do not apply to wounds or damaged skin
- Do not use with other ointments, creams, sprays or liniments
- 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
- Symptoms last more than 7 days or clear up and occur again within a few days.

If pregnant or breast feeding: Ask a health professional before use.

Keep out of reach of children. If swallowed, get medical help, contact a physician or Poison Control Center right away

Directions

- **Adults and children 2 years of age and older:** Rub a thin film over affected

areas not more than 4 times daily; massage not necessary

- **Children under 2 years of age:**Consult a physician

Other Information

Store in a cool dry place.

Inactive Ingredients

Aloe Barbadensis Leaf Extract, Arctium Lappa Root Extract, Arnica Montana Flower Extract, Boswellia Carterii Resin Extract, Brilliant Blue, Calendula Officinalis Extract, Camellia Sinensis Leaf Extract (Green Tea Leaf), Camphor, Carbomer, Glycerin, Ilex Paraguariensis Leaf Extract, Isopropyl Alcohol, Isopropyl Myristate, Melissa Officinalis Leaf Extract, Purified Water, Silicon Dioxide, Tartrazine, Tocopheryl Acetate, Triethanolamine.

Principal Display Panel - 4 oz Pain Relieving Gel

Safetec®

Pain Relieving Gel

For Minor Aches & Pains of Muscles & Joints

Net Wt. 4 oz. (113.4g)

Reorder No. 58002

Manufactured for: Safetec of America, Inc.

Buffalo, NY 14215 | 1-800-456-7077

Made in IndiaKD/739



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PAIN RELIEVING

menthol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:61010-4403
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	4 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
ARCTIUM LAPPA ROOT (UNII: 597E9BI3Z3)	
ARNICA MONTANA (UNII: O80TY208ZW)	
FRANKINCENSE (UNII: R9XLF1R1WM)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
CALENDULA OFFICINALIS FLOWER (UNII: P0M7O4Y7YD)	
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	
CAMPHOR (NATURAL) (UNII: N20HL7Q941)	
CARBOMER HOMOPOLYMER TYPE C (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 4Q93RCW27E)	
GLYCERIN (UNII: PDC6A3C0OX)	
ILEX PARAGUARIENSIS LEAF (UNII: 1Q953B4O4F)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
MELISSA OFFICINALIS LEAF (UNII: 50D2ZE9219)	
WATER (UNII: 059QF0KO0R)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
TRIETHYLAMINE (UNII: VOU728O6AY)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61010-4403-1	113.4 g in 1 TUBE; Type 0: Not a Combination Product	11/01/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M017	11/01/2019	

Labeler - Safetec of America, Inc. (874965262)

Establishment

Name	Address	ID/FEI	Business Operations
Safetec of America, Inc.		874965262	manufacture(61010-4403)

Revised: 2/2024

Safetec of America, Inc.