PAIN RELIEVING ROLL-ON- menthol, unspecified form gel
Safetec of America, Inc.

61010-1550-1, Pain Relieving Roll-on

Drug Facts

Active Ingredients

USP Menthol 7%

Purpose

Topical Analgesic

Uses

Temporary relief of minor aches and pains of muscles and joints.

Warnings

For external use only. Flammable.

Keep away from flame. Keep out of reach of children.

If swallowed get medical help or contact a poison control center right away. Avoid contact with eyes. Do not apply to open wounds or damaged skin. Do not bandage tightly.

Consult a doctor if excessive skin irritation occurs, or if you are prone to allergic reactions to salicylates, including aspirin. If condition worsens, if symptoms persist for more than 7 days or clear up and recur again within a few days, discontinue use of this product and consult a doctor.

Directions

For adults and children 2 years of age and older: Shake well and apply to affected area not more than 3-4 times daily. Will not stain clothing. For children under 2 years of age, consult a doctor.

Other Information

Store at room temperature.

Inactive Ingredients

Eucalyptus Oil, Glycerin, Isopropyl Alcohol, Methyl Salicylate, Purified Water, Tea Tree Oil,

Xanthan Gum.

Principal Display Panel - 3 oz. Bottle Label

Safetec

PAIN RELIEVING

ROLL-ON

FAST-ACTING MUSCLE RELIEF

with Tea Tree & Eucalyptus Oils

Reorder No. 58003

3 fl. oz. (88ml) • Topical Analgesic

PAIN RELIEVING ROLL-ON

menthol, unspecified form gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:61010-1550
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A) (MENTHOL, UNSPECIFIED FORM - UNII:L7T10EIP3A)	MENTHOL, UNSPECIFIED FORM	7 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
EUCALYPTUS OIL (UNII: 2R04ONI662)	
GLYCERIN (UNII: PDC6A3C0OX)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
METHYL SALICYLATE (UNII: LAV5U5022Y)	
WATER (UNII: 059QF0KO0R)	
TEA TREE OIL (UNII: VIF565UC2G)	
XANTHAN GUM (UNII: TTV12P4NEE)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61010-1550-1	88 mL in 1 BOTTLE; Type 0: Not a Combination Product	10/07/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M017	10/07/2019	

Labeler - Safetec of America, Inc. (874965262)

Establishment

Name	Address	ID/FEI	Business Operations
Safetec of America, Inc.		874965262	manufacture(61010-1550)

Revised: 2/2024 Safetec of America, Inc.