ANALGESIC- menthol gel
Safetec of America, 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.

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

Water, Isopropyl Alcohol, Glycerol, Eucalyptus Leaf Oil, Wintergreen Leaf Oil, Peppermint Oil, Coconut Oil, Xanthan Gum.

Principal Display Panel - Pain Relief Roll-On Bottle Label

NDC 61010-XXXX-X

Safetec

**PAIN
RELIEF
ROLL-ON**

MEDICATED FAST-ACTING

For temporary relief of
minor aches and pains

3 fl. oz. (88 ml)

Reorder no. 58001

ANALGESIC

menthol gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:61010-8202
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
menthol (UNII: L7T10EIP3A) (menthol - UNII:L7T10EIP3A)	menthol	70 mg in 1 L

Inactive Ingredients	
Ingredient Name	**Strength**
water (UNII: 059QF0KO0R)	
isopropyl alcohol (UNII: ND2M416302)	
glycerin (UNII: PDC6A3C0OX)	
eucalyptus oil (UNII: 2R04ONI662)	
methyl salicylate (UNII: LAV5U5022Y)	
peppermint oil (UNII: AV092KU4JH)	
coconut oil (UNII: Q9L0O73W7L)	
xanthan gum (UNII: TTV12P4NEE)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61010-8202-0	0.088 L in 1 BOTTLE, WITH APPLICATOR; Type 0: Not a Combination Product	09/01/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	09/01/2018	

Labeler - Safetec of America, Inc. (874965262)

Establishment

Name	Address	ID/FEI	Business Operations
Safetec of America, Inc		874965262	MANUFACTURE(61010-8202)

Revised: 10/2018 Safetec of America, Inc.