

SMOOTH GATOR FOOT AND LEG RUB- camphor (synthetic), menthol cream
Smooth Gator LLC

SMOOTH GATOR Foot and Leg Rub

DRUG FACTS

Active ingredients:

Camphor 4.00%

Menthol 1.25%

Purpose:

Topical Analgesic

Indications:

For the temporary relief of minor aches and pains of the muscles and joints.

Warnings:

- For external use only.
- Avoid contact with eyes.
- If symptoms persist for more than seven days, discontinue use and consult physician.

Keep out of reach of children.

- If swallowed, consult physician.
- Do not apply to wounds or damaged skin.
- Do not bandage tightly.

Directions:

- Adults and children two-years of age or older:
- Children under two-year of age: consult a physician

Apply to affected area not more than three to four times daily.

Additional Information:

Store at room temperature.

Inactive ingredients:

Aloe Barbadensis Leaf (Aloe Vera Gel) Juice, Aqua (Deionized Water), Cetyl Alcohol, Diazolidinyl Urea, Eucalyptus Globulus Oil, Glyceryl Stearate, C13-14 Isoparaffin, Isopropyl Myristate, Laureth-7, Melaleuca Alternifolia (Tea Tree) Oil, Mentha Piperita (Peppermint) Oil, Methyl Paraben, Methyl Salicylate, PEG-100 Stearate, Polyacrylamide, Polysorbate-20, Propyl Paraben, Propylene Glycol, Prunus Amygdalus Dulcis (Sweet Almond) Oil, Retinyl Palmitate (Vitamin A), Rosmarinus Officinalis (Rosemary) Extract, Stearic Acid, Tocopheryl Acetate (Vitamin E), Triethanolamine.

Package Labeling:



SMOOTH GATOR FOOT AND LEG RUB

camphor (synthetic), menthol cream

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:70673-297

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CAMPHOR (SYNTHETIC) (UNII: 5TJD82A1ET) (CAMPHOR (SYNTHETIC) - UNII:5TJD82A1ET)	CAMPHOR (SYNTHETIC)	40 mg in 1 g
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	12.5 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
WATER (UNII: 059QF0KO0R)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	
EUCALYPTUS OIL (UNII: 2R04ONI662)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
C13-14 ISOPARAFFIN (UNII: E4F12ROE70)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
LAURETH-7 (UNII: Z95S6G8201)	
TEA TREE OIL (UNII: VIF565UC2G)	
PEPPERMINT OIL (UNII: AV092KU4JH)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
METHYL SALICYLATE (UNII: LAV5U5022Y)	
PEG-100 STEARATE (UNII: YD01N1999R)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
ALMOND OIL (UNII: 66YXD4DKO9)	
VITAMIN A PALMITATE (UNII: 1D1K0N0VVC)	
ROSEMARY (UNII: IJ67X351P9)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
TROLAMINE (UNII: 9O3K93S3TK)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70673-297-08	227 g in 1 BOTTLE; Type 0: Not a Combination Product	06/01/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M017	06/01/2022	

Labeler - Smooth Gator LLC (029819479)

Revised: 11/2023

Smooth Gator LLC