

**SMOOTH GATOR 60-SECOND PAIN RELIEF- camphor (synthetic),
menthol cream
Smooth Gator LLC**

SMOOTH GATOR 60-second Pain Relief

DRUG FACTS

Active ingredients:

Camphor 3.00%

Menthol 1.25%

Purpose:

Topical Analgesic

Indications:

For the temporary relief of minor aches and pains of the muscles and joints associated with arthritis, simple backache, sprains, bruises and strains.

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:

Acrylates Copolymer, Aloe Barbadensis Leaf (Aloe Vera Gel) Juice, Aqua (Deionized Water), Cetyl Alcohol, Diazolidinyl Urea, Eucalyptus Globulus Oil, Lavandula Angustifolia (Lavender) Oil, Melaleuca Alternifolia (Tea Tree) Oil, Mentha Piperita (Peppermint) Oil, Methyl Paraben, Methyl Salicylate, PEG-8, PEG-100 Stearate, 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:227g



smoothgator

60 second pain relief

MADE WITH ALL NATURAL OILS

wintergreen
aloe vera ■ eucalyptus

net wt 8 oz. (227 g)
www.smoothgator.com



smoothgator

DRUG FACTS		
Active ingredients:		
Camphor	3.00%	Purpose: Topical Analgesic
Menthol	1.25%	Topical Analgesic
Indications: For the temporary relief of minor aches and pains of the muscles and joints associated with arthritis, simple backache, sprains, bruises and strains.		
Warnings:		
<ul style="list-style-type: none">• 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:		
<ul style="list-style-type: none">• Adults and children two-years of age or older: Apply to affected area not more than three to four times daily.• Children under two-years of age: consult a physician		
Additional Information: Store at room temperature.		
Inactive ingredients: Acrylates Copolymer, Aloe Barbadensis Leaf (Aloe Vera Gel) Juice, Aqua (Deionized Water), Cetyl Alcohol, Diazolidinyl Urea, Eucalyptus Globulus Oil, Lavandula Angustifolia (Lavender) Oil, Melaleuca Alternifolia (Tea Tree) Oil, Mentha Piperita (Peppermint) Oil, Methyl Paraben, Methyl Salicylate, PEG-8, PEG-100 Stearate, 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.		

distributed by: smoothgator, llc
5555 Linebaugh Ave., Unit C ■ Tampa, FL 33624

For questions or comments:
727.278.3137
www.smoothgator.com



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Package Labeling:454g



60 second
pain relief

MADE WITH ALL NATURAL OILS

wintergreen
aloe vera ■ eucalyptus

net wt. 16 oz. (454 g)

www.smoothgator.com



DRUG FACTS

Active ingredients:		Purpose:
Camphor	3.00%	Topical Analgesic
Menthol	1.25%	Topical Analgesic

Indications: For the temporary relief of minor aches and pains of the muscles and joints associated with arthritis, simple backache, sprains, bruises and strains.

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:
Apply to affected area not more than three to four times daily.
- Children under two-years of age: consult a physician

Additional Information: Store at room temperature.

Inactive ingredients:

Acrylates Copolymer, Aloe Barbadensis Leaf (Aloe Vera Gel) Juice, Aqua (Deionized Water), Cetyl Alcohol, Diazolidinyl Urea, Eucalyptus Globulus Oil, Lavandula Angustifolia (Lavender) Oil, Melaleuca Alternifolia (Tea Tree) Oil, Mentha Piperita (Peppermint) Oil, Methyl Paraben, Methyl Salicylate, PEG-8, PEG-100 Stearate, 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.

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SMOOTH GATOR 60-SECOND PAIN RELIEF

camphor (synthetic), menthol cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70673-298
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CAMPBOR (SYNTHETIC) (UNII: 5TJD82A1ET) (CAMPBOR (SYNTHETIC) - UNII:5TJD82A1ET)	CAMPBOR (SYNTHETIC)	30 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)	
LAVENDER OIL (UNII: ZBP1YXW0H8)	
TEA TREE OIL (UNII: VIF565UC2G)	
PEPPERMINT OIL (UNII: AV092KU4JH)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
METHYL SALICYLATE (UNII: LAV5U5022Y)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
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:70673-298-08	227 g in 1 BOTTLE; Type 0: Not a Combination Product	06/01/2022	
2	NDC:70673-298-16	454 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