

**SMOOTH GATOR HEAD-EZZ ANALGESIC- menthol cream**  
**Smooth Gator LLC**

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**SMOOTH GATOR Head-Ezz Topical Analgesic Cream**

***DRUG FACTS***

***Active Ingredients:***

Menthol 3.00%

***Purpose***

Topical Analgesic

***Indications:***

For the temporary relief of minor aches and pains.

***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/C10-30 Alkyl Acrylate Crosspolymer, Aloe Barbadensis Leaf (Aloe Vera Gel) Juice, Aqua (Deionized Water), Camphor, Diazolidinyl Urea, Eucalyptus Globulus Oil, Glycerin, Glyceryl Stearate, Glycyrrhiza Glabra (Licorice) Extract, Melaleuca Alternifolia

(Tea Tree) Oil, Mentha Piperita (Peppermint) Oil, Methyl Paraben, Methyl Salicylate, Mineral Oil, Parfum (Fragrance), PEG-100 Stearate, Polysorbate-20, Propyl Paraben, Propylene Glycol, Retinyl Palmitate (Vitamin E), Rosmarinus Officinalis (Rosemary) Extract, Tocopheryl Acetate (Vitamin E), Triethanolamine.

## Package Labelling:



**smooth  
gator**

**HEAD-EZZ  
EXTERNAL  
ANALGESIC CREAM**

made with all natural oils

peppermint n lavender

2 FLOZ/ 60 ML


[www.smoothgator.com](http://www.smoothgator.com)

directions: apply directly to affected area;  
do not use more than four times per day.

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**distributed by: smooth gator, llc**  
5555 Linebaugh Ave., Unit C • Tampa, FL 33624

For questions or comments:  
**727.278.3137 • [www.smoothgator.com](http://www.smoothgator.com)**



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## SMOOTH GATOR HEAD-EZZ ANALGESIC

menthol cream

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:70673-501
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>MENTHOL</b> (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	30 mg in 1 mL

### Inactive Ingredients

Ingredient Name	Strength
<b>ALOE VERA LEAF</b> (UNII: ZY81Z83H0X)	

<b>WATER</b> (UNII: 059QF0KO0R)
<b>DIAZOLIDINYL UREA</b> (UNII: H5RIZ3MPW4)
<b>EUCALYPTUS OIL</b> (UNII: 2R04ONI662)
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)
<b>GLYCERYL MONOSTEARATE</b> (UNII: 230OU9XXE4)
<b>LICORICE</b> (UNII: 61ZBX54883)
<b>MELALEUCA ALTERNIFOLIA LEAF</b> (UNII: G43C57162K)
<b>PEPPERMINT OIL</b> (UNII: AV092KU4JH)
<b>METHYLPARABEN</b> (UNII: A2I8C7HI9T)
<b>METHYL SALICYLATE</b> (UNII: LAV5U5022Y)
<b>MINERAL OIL</b> (UNII: T5L8T28FGP)
<b>PEG-100 STEARATE</b> (UNII: YD01N1999R)
<b>POLYSORBATE 20</b> (UNII: 7T1F30V5YH)
<b>PROPYLPARABEN</b> (UNII: Z8IX2SC1OH)
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)
<b>.ALPHA.-TOCOPHEROL</b> (UNII: H4N855PNZ1)
<b>ROSEMARY</b> (UNII: IJ67X351P9)
<b>TROLAMINE</b> (UNII: 9O3K93S3TK)

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70673-501-00	60 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/13/2024	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M017	06/13/2024	

**Labeler** - Smooth Gator LLC (029819479)

### Establishment

Name	Address	ID/FEI	Business Operations
Pure Source, LLC		080354456	manufacture(70673-501)

Revised: 6/2024

Smooth Gator LLC