

**GRANULOTION MEDICATED- menthol, zinc oxide lotion**  
**GL HEALTH, INC.**

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**Granulotion Medicated Lotion**

**DRUG FACTS**

**Active Ingredients:**

Menthol 0.11%, Zinc Oxide 5.1%

**Purpose:**

External analgesic, Anti-itch, Skin protectant, Anorectal astringent

**USES:**

Helps relieve local itching and discomfort of the perianal area. Temporarily forms a protective barrier over inflamed tissues to help prevent drying of tissues. For the temporary relief of pain, burning and skin irritation. Can help distract the pain and may provide cooling sensation.

**WARNINGS:**

For external use only

- If condition worsens or does not improve within 7 days, consult a doctor
  - Do not exceed the recommended daily dose unless directed by a doctor
  - In case of bleeding, consult a doctor promptly
  - Certain persons can develop allergic reactions to ingredients in this product. If the symptom being treated does not subside or if redness, irritation, swelling, pain or other symptoms develop or increase, discontinue use and consult a doctor
- **Keep out of reach of children.**

**DIRECTIONS:**

When practical, cleanse the affected area with mild soap and warm water. Pat or allow to air dry. Apply a layer of GranuLotion® up to 6 times daily for inflammation, 1 time per day for continued site maintenance. Use a soft tipped applicator for hard to reach areas. Repeat as needed to protect the skin or until the condition resolves.

**INACTIVE INGREDIENTS:**

Aloe Barbadensis Leaf (Aloe Vera Gel) Juice, Aqua (Deionized Water), Betaglacans, Cetearyl Alcohol, Ethylhexylglycerin, Glycerin, Glyceryl Stearate, Glycrrhiza Glabra (Licorice Extract, Helianthus Annuus (Sunflower) Oil, Melaleuca Alternifolia (Tea Tree) Oil,

Olea Europaea (Olive) Oil, PEG-100 Stearate, Phenoxyethanol, Polysorbate-20, Potassium Alum, Tocopheryl Acetate (Vitamin E), FDandC Blue 1.

**Package Labeling:**

Non Printing Area



**GranuLotion™**

**MEDICATED LOTION**

*Protects & soothes, anti-itch, helps shrink tissues*

Non Printing Area

GRANULOTION.COM

NET WT 0.5 OZ (14 g)

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DISTRIBUTED BY: GranuLotion Global, Inc. Tinley Park, IL PATENT PENDING: NDC #65121-885-23

**GRANULOTION MEDICATED**

menthol, zinc oxide lotion

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:82897-544
<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	1.1 mg in 1 g
<b>ZINC OXIDE</b> (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	51 mg in 1 g

**Inactive Ingredients**

Ingredient Name	Strength
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<b>ALOE VERA LEAF</b> (UNII: ZY81Z83H0X)
<b>WATER</b> (UNII: 059QF0KO0R)
<b>CETOSTEARYL ALCOHOL</b> (UNII: 2DMT128M1S)
<b>ETHYLHEXYLGLYCERIN</b> (UNII: 147D247K3P)
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)
<b>GLYCERYL MONOSTEARATE</b> (UNII: 230OU9XXE4)
<b>LICORICE</b> (UNII: 61ZBX54883)
<b>HELIANTHUS ANNUUS FLOWERING TOP</b> (UNII: BKJ0J3D1BP)
<b>TEA TREE OIL</b> (UNII: VIF565UC2G)
<b>OLIVE OIL</b> (UNII: 6UYK2W1W1E)
<b>PEG-100 MONOSTEARATE</b> (UNII: YD01N1999R)
<b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)
<b>POLYSORBATE 20</b> (UNII: 7T1F30V5YH)
<b>POTASSIUM ALUM</b> (UNII: 1L24V9R23S)
<b>.ALPHA.-TOCOPHEROL ACETATE</b> (UNII: 9E8X80D2L0)
<b>FD&amp;C BLUE NO. 1</b> (UNII: H3R47K3TBD)

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:82897-544-00	14 g in 1 TUBE; Type 0: Not a Combination Product	10/14/2024	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M015	10/14/2024	

**Labeler** - GL HEALTH, INC. (086010932)

Revised: 10/2024

GL HEALTH, INC.