

## **GRANULOTION- menthol, zinc oxide lotion**

**Pure Source, LLC**

*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.*

-----

### **GranuLotion medicated lotion**

### **GranuLotion medicated lotion**

#### **Active Ingredients**

Menthol 0.11%

Zinc Oxide 5.1%

#### **Purpose**

External analgesic / Anti-itch

Skin protectant / Anorectal astringent

#### **Uses:**

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

#### **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 Barbadosensis Leaf (Aloe Vera Gel) Juice, Aqua (Deionized Water), Betaglacans, Cetearly 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.

GranuLotion medicated lotion 1oz/28.349g (65121-885-23)



GranuLotion<sup>TM</sup>

*medicated lotion*

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

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

*NET WT. 1 OZ. (28.349g)*



Drug Facts	GranuLotion®	1oz.
<b>Active Ingredients</b>		<b>Purpose</b>
Menthol 0.11%.....		External analgesic / Anti-itch
Zinc Oxide 5.1%.....		Skin protectant / Anorectal astringent
<p><b>Uses:</b> Helps relieve the local itching and discomfort of the perianal area. Temporarily forms a protective barrier over inflamed tissues to help prevent the drying of tissues. For the temporary relief of pain, burning and skin irritation. Can help distract from pain and may provide a cooling sensation.</p>		
<p><b>Warnings:</b> 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.</p>		
<p><b>Directions:</b> 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.</p>		
<p><b>Inactive ingredients:</b> Aloe Barbadosensis Leaf (Aloe Vera Gel) Juice, Aqua (Deionized Water), Betaglacans, Cetearly 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), FD&amp;C Blue #1.</p>		

**Distributed By: \* GranuLotion Global, Inc.™ \* 15941 Harlem Ave. #355 Tinley Park, IL 60477 \***  
**www.granulotion.com**  
**Patent Pending \* NDC#**

## GRANULOTION

menthol, zinc oxide lotion

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:65121-885
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	0.11 g in 100 g
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	5.1 g in 100 g

### Inactive Ingredients

Ingredient Name	Strength
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
WATER (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>SUNFLOWER OIL</b> (UNII: 3W1JG795YI)
<b>TEA TREE OIL</b> (UNII: VIF565UC2G)
<b>OLIVE OIL</b> (UNII: 6UYK2W1W1E)
<b>PEG-100 STEARATE</b> (UNII: YD01N1999R)
<b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)
<b>POLYSORBATE 20</b> (UNII: 7T1F30V5YH)
<b>POTASSIUM ALUM</b> (UNII: 1L24V9R23S)
<b>.ALPHA.-TOCOPHEROL</b> (UNII: H4N855PNZ1)
<b>FD&amp;C BLUE NO. 1</b> (UNII: HBR47K3TBD)

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65121-885-23	1 in 1 BOX	02/09/2017	
1		28.349 g in 1 BOTTLE; Type 0: Not a Combination Product		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part346	03/26/2014	

**Labeler** - Pure Source, LLC (080354456)

### Establishment

Name	Address	ID/FEI	Business Operations
Pure Source, LLC		080354456	manufacture(65121-885)

Revised: 2/2017

Pure Source, LLC