

GRANULOTION HEMORRHOIDAL- menthol, zinc oxide lotion
GL Health, Inc.

GRANULOTION Hemorrhoidal Lotion

DRUG FACTS

ACTIVE INGREDIENTS

Menthol 0.11%

Zinc Oxide 5.1%

PURPOSE

Analgesic, Anesthetic and Antipruritic

Astringent

USE

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, 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.

Package Labeling:

DRUG FACTS		
ACTIVE INGREDIENTS	PURPOSE	USE
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DISTRIBUTED BY GranuLotion Global, Inc. 15941 S. Harlem Ave. #355 Tinley Park, IL 60477 PATENT PENDING NDC #65121-885-23		



HEMORRHOIDAL LOTION

NET CONTENT 0.11 FL OZ / 3.3 ML

GRANULOTION HEMORRHOIDAL			
menthol, zinc oxide lotion			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:82897-293
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	1.1 mg in 1 mL
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	51 mg in 1 mL

Inactive Ingredients

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:82897-293-00	3.3 mL in 1 PACKET; Type 0: Not a Combination Product	05/20/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M015	05/20/2022	

Labeler - GL Health, Inc. (086010932)