

**MENTHOL AND ZINC OXIDE- menthol and zinc oxide ointment
GERI-GENTLE CORPORATION**

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.

GG Tender Calm

**Menthol 0.44% w/w.....External Analgesic
Zinc Oxide 20.625% w/w..... Skin Protectant**

Active Ingredients

**Menthol 0.44% w/w
Zinc Oxide 20.625% w/w**

Purpose

Menthol 0.44% w/w.....External Analgesic
Zinc Oxide 20.625% w/w..... Skin Protectant

uses

A moisture barrier that prevents and helps heal skin irritations from;

- urine
- diarrhea
- perspiration
- fistula drainage
- feeding tube site leakage
- wound drainage (peri-wound skin)
- minor burns
- cuts
- scrapes
- itching

Warnings:

■For external use only ■Not for deep or puncture wounds ■Avoid contact with eyes

Stop use and ask a doctor if

■Condition worsens

■Symptoms last more than 7 days or clear up and occur again within a few days

Keep Out Of Reach Of Children

Keep Out Of Reach Of Children

If swallowed , get medical help or contact a Poison Control Center right away.

Dosage & Administration:

- Clean skin with mild skin cleanser
- Pat dry or allow to air dry
- Apply a thin layer of Calasoothe to reddened or irritated skin 2-4 times daily, or after each incontinent episode or diaper change to promote comfort and long lasting protection

Inactive Ingredients

Calamine, Glycerine, Lanolin, Light Liquid Paraffin, Petrolatum, Thymol, Tocopheryl Acetate

Principal Display Panel

Drug Facts	
Active Ingredients	Purpose
Menthol 0.44% w/w	External Analgesic
Zinc Oxide 20.625% w/w	Skin Protectant
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Warnings ■ For external use only ■ Not for deep or puncture wounds ■ Avoid contact with eyes	
Stop use and ask a doctor if ■ Condition worsens ■ Symptoms last more than 7 days or clear up and occur again within a few days	
Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.	
Directions ■ Cleanse skin with mild skin cleanser ■ Pat dry or allow to air dry ■ Apply a thin layer of Skin Protectant to reddened or irritated skin 2-4 times daily, or after each incontinent episode or diaper change to promote comfort and long lasting protection	
Other Information ■ Store at room temperature 20°-25°C (68°-77°F)	
Inactive Ingredients Calamine, Glycerine, Lanolin, Light Liquid Paraffin, Petrolatum, Thymol, Tocopheryl Acetate	

Patient Name:
Room #:



GeriGentle®

Tender Calm

**Skin Protectant
with Cooling Menthol
and Zinc Oxide**



SOOTHES AND
PROMOTES HEALING

4 Oz. (113g)

Manufactured for the:
Geri Gentle Corporation
5 Hollywood Ct,
South Plainfield, NJ 07080
718-802-1085
www.ggentle.com
Made In India

HR/DRUGS 1105-OSP(H)



Reorder No.
04121

MENTHOL AND ZINC OXIDE

menthol and zinc oxide ointment

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69771-013
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	0.44 g in 100 g
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	20.625 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
LANOLIN (UNII: 7EV65EAW6H)	
LIGHT MINERAL OIL (UNII: N6K5787QVP)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
THYMOL (UNII: 3J50XA376E)	
PETROLATUM (UNII: 4T6H12BN9U)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69771-013-23	113 g in 1 TUBE; Type 0: Not a Combination Product	08/17/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part347	08/17/2022	

Labeler - GERI-GENTLE CORPORATION (080367686)

Revised: 8/2022

GERI-GENTLE CORPORATION