

## **CALMOSEPTINE - zinc oxide and menthol ointment**

**Physicians Total Care, Inc.**

*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.*

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### **Drug Facts**

#### **Active Ingredients**

Menthol 0.44%

Zinc Oxide 20.625%

#### **Purpose**

External analgesic / Anti-itch

Skin protectant / Anorectal astringent

#### **Uses**

**Uses:** A moisture barrier that prevents and helps heal skin irritation from:

urine, diarrhea, perspiration, fistula damage, feeding tube site leakage,

wound drainage (peri-wound skin), minor burns, cuts, scrapes, itching

#### **Warnings**

**Warnings: For external use only.** Not for deep or puncture wounds. Avoid contact with eyes.

In case of accidental ingestion contact a physician or poison control center immediately. If condition worsens or does not improve within 7 days, consult a doctor.

Keep out of reach of children

#### **Directions**

**Directions:** Cleanse skin gently with mild skin cleanser. Pat dry or allow to air dry. Apply

a thin layer of Calmoseptine Ointment 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**

**Inactive ingredients:** Calamine, chlorothymol, glycerin, lanolin, phenol,

sodium bicarbonate, and thymol in a suitable ointment base

### **PRINCIPAL DISPLAY PANEL**

Calmoseptine Ointment

Menthol 0.44%

Zinc Oxide 20.6%  
71 gram tube  
NDC 54868-5287-0



**Additional barcode labeling by:**  
Physicians Total Care, Inc.  
Tulsa, Oklahoma 74146

## CALMOSEPTINE

zinc oxide and menthol ointment

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:54868-5287(NDC:0799-0001)
Route of Administration	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	20.6 g in 113 g
MENTHOL (UNII: L7T10EIP3A) (LEVOMENTHOL - UNII:BZ1R15MTK7)	MENTHOL	0.44 g in 113 g

### Inactive Ingredients

Ingredient Name	Strength
FERRIC OXIDE RED (UNII: 1K09F3G675)	
Chlorothymol (UNII: LJ25TI0CVT)	
Glycerin (UNII: PDC6A3C0OX)	
Lanolin (UNII: 7EV65EAW6H)	
Phenol (UNII: 339NCG44TV)	
Sodium Bicarbonate (UNII: 8MDF5V39QO)	
Thymol (UNII: 3J50XA376E)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
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<b>1</b>	NDC:54868-5287-0	71 g in 1 TUBE		
<b>Marketing Information</b>				
<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>		<b>Marketing Start Date</b>	<b>Marketing End Date</b>
OTC monograph final	part347		07/19/2006	

**Labeler** - Physicians Total Care, Inc. (194123980)

<b>Establishment</b>			
<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
Physicians Total Care, Inc.		194123980	relabel

Revised: 6/2012

Physicians Total Care, Inc.