

MENTHOL AND ZINC OXIDE - menthol and zinc oxide ointment
Blossom Pharmaceuticals

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.

Calasoothe Ointment

Active Ingredient	Purpose
Menthol 0.44% v/v	External Analgesic First Aid Antiseptic Antipuritic
Zinc Oxide 20.625% v/v	Skin Protectant Moisture Barrier

Purpose:

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:

Keep out of reach of children

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

Indications & Usage

- Not for deep or puncture wounds.
- Avoid contact with eyes.
- If condition worsens or does not improve within 7 days, consult a doctor

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

Keep Out Of Reach Of Children

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

Inactive Ingredients

Inactive Ingredients: Calamine, Glycerine, Phenol, Lanolin, Heavy Liquid Paraffin, Sodium Bicarbonate, Thymol, White Soft Paraffin

Principal Display Panel

Principal Display Panel - Ointment

Blossom1275.jpg

Blossom

PHARMACEUTICALS

Skin Protectant / Moisture Barrier Cream
Protects, Soothes and Promotes Healing

NDC# 61767-234-03

Reorder No.1275
 Net Wt. 4 OZ (113g)



GO/DRUGS/911/L

Drug Facts		ROOM #
Active Ingredient	Purpose	
Menthol 0.44%	External Analgesic, First Aid	
.....	Antiseptic, Antipruritic	
Zinc Oxide 20.625%	Skin Protectant,	
.....	Moisture Barrier	
Uses: A moisture barrier that prevents & 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 • If condition worsens or does not improve within 7 days, consult a doctor.		
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 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		
Other information • Store at room temperature 20° - 25°C (68° - 77°F)		
Tamper Evident Do not use if tube is broken or damaged.		
Inactive ingredients Calamine, Glycerine, Phenol, Lanolin, Heavy Liquid Paraffin, Sodium Bicarbonate, Thymol, White Soft Paraffin.		

PATIENT NAME:

Manufactured by:
Blossom Pharmaceuticals
 Karaswade, Tivim, Bardez, Tivi
 Gao, Goa India 403526
 Made in India

MENTHOL AND ZINC OXIDE

menthol and zinc oxide ointment

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:61767-234
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	.44 g in 100 g
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	21 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	
PHENOL (UNII: 339NCG44TV)	
LANOLIN (UNII: 7EV65EAW6H)	
MINERAL OIL (UNII: T5L8T28FGP)	
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	
THYMOL (UNII: 3J50XA376E)	
PETROLATUM (UNII: 4T6H12BN9U)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61767-234-01	3.5 g in 1 POUCH		
2	NDC:61767-234-02	71 g in 1 JAR		
3	NDC:61767-234-03	113 g in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part347	10/11/2014	

Labeler - Blossom Pharmaceuticals (677381470)

Revised: 10/2014

Blossom Pharmaceuticals