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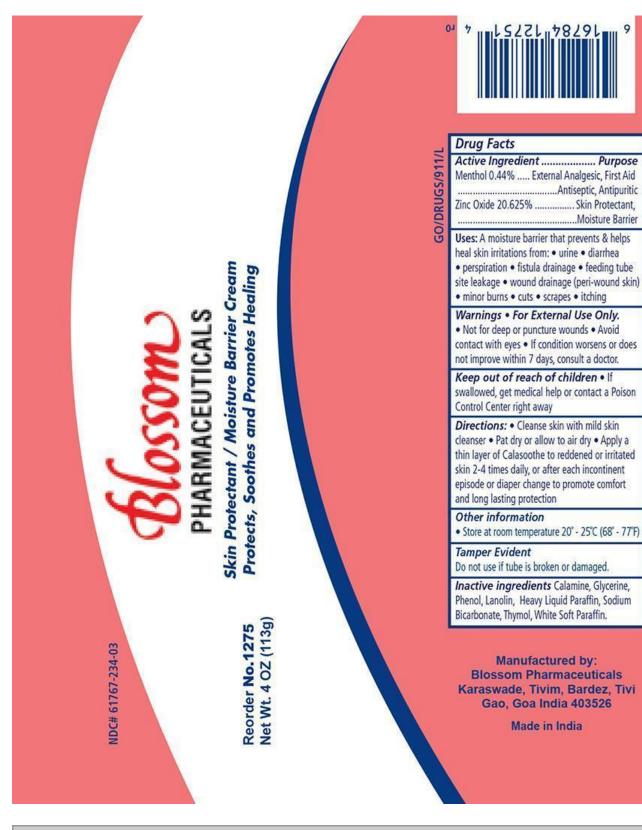
If swallowed, get medical help or contact a Poison Control Center right away.

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



ROOM #

PATIENT NAME:

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 ND	C:61767-234-01	3.5 g in 1 POUCH			
2 ND	C:61767-234-02	71 g in 1 JAR			
3 ND	C:61767-234-03	113 g in 1 TUBE			

Marketing Information					
Application Number or Monograph Citation	Marketing Start Date	Marketing End Date			
part347	10/11/2014				
	Application Number or Monograph Citation	Application Number or Monograph Citation Marketing Start Date			

Labeler - Blossom Pharmaceuticals (677381470)

Revised: 10/2014

Blossom Pharmaceuticals