

CALMAFX MOISTURE BARRIER- menthol, calamine, zinc oxide ointment

First Choice Medical Supply

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.

CalmaFX Moisture Barrier Ointment Drug Facts

Active Ingredients

Menthol 0.45%

Calamine 2%

Zinc Oxide 18%

Purpose

External Analgesic, Skin Protectant

Uses

A moisture barrier that prevents and helps protect skin irritations from

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

Warnings

- **For external use only.**
- When using this product
- do not get into eyes.

Stop use and ask 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

When practical, gently cleanse and dry area.

- **Adults:** Apply externally to affected area up to 6 times daily or after each incontinent episode or diaper change.
- **Children under 12 years:** Consult a doctor.

Other Information

Store at 15-30°C (59-86°F)

Inactive Ingredients:

Beeswax, Disodium EDTA, Glycerin, Lanolin, Methylparaben, Mineral Oil, Petrolatum, Propylparaben, Purified Water, Sodium Borate, Sorbitan Sesquioleate

Questions or Comments?

First Choice Medical Supply

127 Interstate Dr.

Richland, MS 39218

800-809-4556 or visit www.fcms.com

Item # 33433

Images of representative artwork

CalmaxSachet.jpg

REORDER# 33433

CalmaEx
Moisture Barrier Ointment

Moisture Barrier Ointment

**Soothes, Protects and
Moisturizes Skin**

TREATMENT

First Choice medical supply

NET WT 5g (0.17 OZ)

Drug Facts

Active Ingredient	Purpose
Menthol 0.45%.....	External Analgesic
Calamine 2%	Skin Protectant
Zinc Oxide 18%.....	Skin Protectant

Drug Facts (continued)

Uses

A moisture barrier that prevents and helps protect skin irritations from ■ urine ■ diarrhea ■ perspiration ■ fistula drainage ■ feeding tube site leakage ■ wound drainage ■ minor burns ■ cuts ■ scrapes ■ itching.

Warnings ■ **For external use only.** ■ When using this product ■ do not get into 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.

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REORDER# 32460

CalmaEx
Moisture Barrier Ointment

Moisture Barrier Ointment

Soothes, Protects
Moisturizes Skin

TREATMENT

First Choice medical supply

Net Wt. 4oz. (113g)

Drug Facts

Active Ingredient	Purpose
Menthol 0.45%	External Analgesic
Calamine 2%	Skin Protectant
Zinc Oxide 18%	Skin Protectant

Uses

A moisture barrier that prevents and helps protect skin irritations from ■ urine ■ diarrhea ■ perspiration ■ fistula drainage ■ feeding tube site leakage ■ wound drainage ■ minor burns ■ cuts ■ scrapes ■ itching. Dries oozing/weeping of poison: ■ ivy ■ oak ■ sumac.

Warnings

■ For external use only. ■ When using this product ■ do not get into 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

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Other information

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Inactive ingredients

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FCMS32460

CALMAFX MOISTURE BARRIER

menthol, calamine, zinc oxide ointment

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:75904-3246
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	4.5 mg in 1 g

FERRIC OXIDE RED (UNII: 1K09F3G675) (FERRIC OXIDE RED - UNII:1K09F3G675)	FERRIC OXIDE RED	20 mg in 1 g
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	180 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
YELLOW WAX (UNII: 2ZA36H0S2V)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
GLYCERIN (UNII: PDC6A3C0OX)	
LANOLIN (UNII: 7EV65EAW6H)	
METHYL PARABEN (UNII: A2I8C7HI9T)	
MINERAL OIL (UNII: T5L8T28FGP)	
PETROLATUM (UNII: 4T6H12BN9U)	
PROPYL PARABEN (UNII: Z8IX2SC1OH)	
WATER (UNII: 059QF0K00R)	
SODIUM BORATE (UNII: 91MBZ8H3QO)	
SORBITAN SESQUIOLEATE (UNII: 0W8RRI5W5A)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:75904-3246-3	5 g in 1 POUCH		
2	NDC:75904-3246-0	113 g in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part347	02/28/2011	

Labeler - First Choice Medical Supply (117734405)

Registrant - Summit Industries, Inc. (003279189)

Establishment

Name	Address	ID/FEI	Business Operations
Summit Industries, Inc.		003279189	manufacture(75904-3246)