CALMAFX MOISTURE BARRIER- menthol, ferric oxide red and 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

CalmafxSachet.jpg



Zinc Oxide 18%.....Skin Protectant

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. 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 dipper change. Children under 12 years: Consult a doctor. Other information Store at 15°C - 30°C (59°F - 86°F). Inactive ingredients Beeswax, Disodium EDTA, Glycerin, Lanolin, Methylparaben, Mineral Oi, Petrolatum, Propylparaben, Purified Wate Sodium Borate, Sorbitan Sesquioleate. First Choice Medical Supply ce medical 127 Interstate Dr. Richland MS 3931 Richland, MS 39218

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

Drug Facts (continued)

calmafxtube.jpg

REORDER# 32460



Moisture Barrier Ointment

Soothes, Protects Moisturizes Skin

TREATMENT



Net Wt. 4oz. (113g)

Drug Facts

Active Ingredient	Purpose
Menthol 0.45%	
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 pozing/weeping of poison: ■ ivv■ oak ■

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

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°C - 30°C (59°F - 86°F).

Inactive ingredients

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



First Choice Medical Supply 127 Interstate Dr., Richland, MS 39218 800-809-4556 www.fcms.com



CALMAFX MOISTURE BARRIER

menthol, calamine, zinc oxide ointment

Product Information

Product TypeHUMAN OTC DRUG LABELItem Code (Source)NDC:75904-3246

Route of Administration TOPICAL DEA Schedule

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
	3 m3 m 7 m 7 m	

MENTHOL (MENTHOL)

4.5 mg in 1 s

FERRIC OXIDE RED (FERRIC OXIDE RED)	FERRIC OXIDE RED	20 mg in 1 g
ZINC OXIDE (ZINC OXIDE)	ZINC OXIDE	180 mg in 1 g

Inactive Ingredients				
Ingredient Name	Strength			
YELLOW WAX				
EDETATE DISO DIUM				
GLYCERIN				
LANOLIN				
METHYLPARABEN				
MINERAL OIL				
PETROLATUM				
PROPYLPARABEN				
WATER				
SODIUM BORATE				
SORBITAN SESQUIO LEATE				

F	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)	

Revised: 3/2013 First Choice Medical Supply