

VERASEPTINE MULTIPURPOSE MOISTURE BARRIER- zinc oxide cream
LTC Products, 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.

VeraSeptine Multipurpose Moisture Barrier

Zinc Oxide 21%....Skin Protection

Petrolatum, Water, Mineral Oil, Glyceryl Stearate, Di-C12-15 Alkyl Fumarate, Glycerin, Dimethicone, Lanolin, Menthol, Phenol, Thymol, Chlorothymol, Tocopheryl Acetate, Caprylic/Capric Triglyceride, Sunflower Oil, Isostearic Acid, Polyhydroxystearic Acid, Lecithin, Polyglyceryl-3 Polyricinoleate, Sodium Bicarbonate, Iron Oxide

A moisture barrier that prevents and helps heal skin irritations from

- Urine
- diarrhea
- perspiration
- minor burns

For external use only.

- Not for deep or puncture wounds
- Avoid contact with eyes
- Keep out of the reach of children
- 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 physician.

Cleanse skin gently with mild skin cleanser, such as PeleVerus Wound Cleanser or Array Perineal Wash. Pat dry or allow to air dry. Apply a thin layer of VeraSeptine Moisture Barrier to reddened or irritated skin 2-4 times daily, or after each incontinent episode or diaper change to promote comfort and long lasting protection.

A moisture barrier that prevents and helps heal skin irritations from urine, diarrhea, perspiration, minor burns, fistula drainage, feeding tube site leakage, wound drainage (peri-wound skin), cuts, scrapes, itching

Avoid contact with the eyes.

Keep out of the reach of children. 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 physician.

Keep out of the reach of children. In case of accidental ingestion contact a physician or poison control center immediately



Front



Back

Catalog Qty: 144/box Net Contents 3.5 gm

VeraSeptine

Multipurpose Moisture Barrier

Protects, soothes, helps promote healing of skin irritation

Uses:
A moisture barrier that prevents & helps heal skin irritations from:

- urine - minor burns
- diarrhea - fistula drainage
- perspiration - feeding tube site leakage
- wound drainage (peri-wound skin)
- cuts - itching

Catalog No. 27560 Made in USA

Qty: 144/box Net Contents 3.5 gm Qty: 144/box Net Contents 3.5 gm Qty: 144/box Net Contents 3.5 gm Qty: 144/box Net Contents 3.5 gm

Catalog No. 27560 Made in USA

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4" 4" 3 7/8"

VeraSeptine™
Multipurpose Moisture Barrier

DRUG FACTS

Active Ingredient	Purpose
Zinc Oxide 21%	Skin Protection

Uses:
A moisture barrier that prevents & helps heal skin irritations from:

- urine - minor burns
- diarrhea - fistula drainage
- perspiration - feeding tube site leakage
- wound drainage (peri-wound skin)
- cuts - itching

Warnings:
For external use only.
• Not for use on puncture wounds
• Avoid contact with eyes
• Keep out of the reach of children
• 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 physician.

Directions:
Cleanse skin gently with mild antibacterial cleanser such as Pediatric Mildest Cleanser or Aqual Pediatric Wash. Pat dry or allow to air dry. Apply a thin layer of VeraSeptine Moisture Barrier to redness or irritated skin 2-4 times daily, or after each voiding episode or diaper change to provide comfort and long lasting protection.

Inactive Ingredients: Petrolatum, Hexa-Methyl-Cyclotri-Siloxane, Di-C12-18-Alkyl-Ethanolamine, Stearic Acid, Zinc Oxide, Menthol, Thymol, Octylphenoxypolyethoxyethanol, Caprylic/Capric Triglyceride, Barbituric Acid, Isobutyl Alcohol, Polyhydroxyethyl Acrylate, Laureth-9, Polyglyceryl-3 Polydistearate. Indian Harbor Beach, FL 33438

Questions: Call 1-800-800-2381

Recall of Controlled Substances Temperature Sensitive Drug (CSSTP)
Reorder No.: 27560
NDC 61598-200-01
VERASEPTINE LLC
Cincinnati, OH
www.veraseptine.com

3 7/8"

61598-200-01.jpg

VERASEPTINE MULTIPURPOSE MOISTURE BARRIER			
zinc oxide cream			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:61598-200
Route of Administration	TOPICAL		
Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	21 g in 100 g	
Inactive Ingredients			
Ingredient Name	Strength		
PETROLATUM (UNII: 4T6H12BN9U)			
MINERAL OIL (UNII: T5L8T28FGP)			
DIMETHICONE (UNII: 92RU3N3Y1O)			
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)			
LANOLIN (UNII: 7EV65EAW6H)			
MENTHOL (UNII: L7T10EIP3A)			
WATER (UNII: 059QF0K00R)			
GLYCERIN (UNII: PDC6A3C0OX)			

PHENOL (UNII: 339NCG44TV)	
THYMOL (UNII: 3J50XA376E)	
CHLOROTHYMOL (UNII: LJ25TI0CVT)	
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
DI-C12-15 ALKYL FUMARATE (UNII: A1CB3Z898P)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61598-200-10	100 g in 1 TUBE		
2	NDC:61598-200-01	144 in 1 BOX		
2	NDC:61598-200-00	3.5 g in 1 PACKET		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part347	10/07/2013	

Labeler - LTC Products, Inc. (967367991)

Registrant - Kutol Products Company, Inc. (004236139)

Establishment			
Name	Address	ID/FEI	Business Operations
Kutol Products Company, Inc.		004236139	manufacture(61598-200) , analysis(61598-200) , label(61598-200) , pack(61598-200)

Revised: 5/2014

LTC Products, Inc.