GERI PROTECT- petrolatum ointment Geritrex LLC

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.

Geri Protect

Active Ingredient:

Petrolatum 74%

Purpose

Skin Protectant

Protects skin against chafing and reduces rashes. It helps the skin retain needed moisture, while softening and soothing damaged irritated skin. Protects skin against irritating substances that may come in contact with elbows, heals, hands, and private areas of your body. Now has fragrance free formula for sensitive skin. It assists with the healing

IWARNING: FOR EXTERNAL USE ONLY

IKeep out of reach of children

Caution: Avoid eye contact. If contact - flush eyes thoroughly with water. If local sensitivity develops discontinue use.

Directions: Clean skin. Apply geri-protect ointment, liberally to affected area 2-4 times daily or more frequently as needed.

Inactive Ingredients: IAloe vera, lanolin, mineral oil, Paraffin wax, PCMX Powder, Phenoxyethanol, Sodium Borate, Vitamins A, D, and E, water deionized, Zinc Oxide

GERI PROTECT

Drug Facts

Active Ingredient:.....Purpose
Petrolatum 74% Skin Protectant

Uses: Protects skin against chafing & reduces rashes. It helps the skin retain needed moisture, while softening and soothing damaged irritated skin. Protects skin against irritating substances that may come in contact with elbows, heals, hands and private areas of your body. Now has fragrance free formula for sensitive skin. It assists with the healing process against skin break down caused by friction, chronic dryness, diaper rashes and harsh irritants. Helps to maintain healthy skin. It also serves as an excellent water proof barrier for the delicate skin of babies.

Warnings: FOR EXTERNAL USE ONLY. Keep out of reach of children.

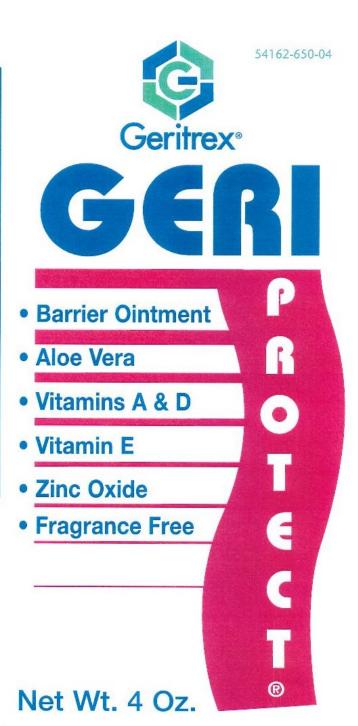
Caution: Avoid eye contact. If contact- flush eyes thoroughly with water. If local sensitivity develops discontinue use.

Directions: Clean skin. Apply geri-Protect ointment, liberally to affected areas 2-4 times daily or more frequently as needed.

Inactive Ingredients: Aloe Vera, Lanolin, Mineral oil, Paraffin Wax, PCMX Powder, Phenoxyethanol, Sodium Borate, Vitamins A, D & E, Water deionized, Zinc Oxide







GERI PROTECT

petrolatum ointment

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:54162-650
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
PETROLATUM (UNII: 4T6H12BN9U) (PETROLATUM - UNII:4T6H12BN9U)	PETROLATUM	87.32 g in 118 g

Inactive Ingredients			
Ingredient Name	Strength		
ALOE VERA LEAF (UNII: ZY8 1Z8 3H0 X)			
LANOLIN (UNII: 7EV65EAW6H)			
MINERAL OIL (UNII: T5L8T28FGP)			
PARAFFIN (UNII: 19 O 0 E 3 H 2 Z E)			
PHENO XYETHANOL (UNII: HIE492ZZ3T)			
SODIUM BORATE (UNII: 91MBZ8H3QO)			
VITAMIN A (UNII: 81G40H8B0T)			
VITAMIN D (UNII: 9 VU1KI44GP)			
WATER (UNII: 059QF0KO0R)			
ZINC OXIDE (UNII: SOI2LOH54Z)			
ALPHA-TOCOPHEROL (UNII: H4N855PNZ1)			
CHLOROXYLENOL (UNII: 0F32U78 V2Q)			

Pac	kaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1 N	DC:54162-650-04	118 g in 1 PACKAGE; Type 0: Not a Combination Product		

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph final	part347	07/31/2015		

Labeler - Geritrex LLC (112796248)

Establishment					
Name	Address	ID/FEI	Business Operations		
Geritrex LLC		112796248	manufacture(54162-650)		

Revised: 12/2015 Geritrex LLC