PERIGUARD- otc skin protectant drug products ointment DermaRite Industries, 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.

DRUG LISTING:PERIGUARD OINTMENT

Active Ingredient:

Petrolatum 49.9%

Purpose:

Skin Protectant

Uses:

A moisture barrier that prevents and helps treat skin irritation from urine, feces, perspiration, conditions associated with diaper rash from incontinence.

Warnings:

- For external use only.
- Avoid contact with eyes. In case of contact, flush thoroughly with water.
- **Stop use and ask doctor if** condition worsens or does not improve within 7 days.
- In case of accidental ingestion contact a physician or Poison Control Center right away.

Warnings:

• **Keep out of reach of children.** If swallowed, contact a physician or Poison Control Center right away.

Directions:

Cleanse skin gently with a mild cleanser. Pat dry or allow to dry. Apply a thin layer of ointment to the affected area as necessary, or after each incontinent episode or diaper change to promote comfort and long lasting protection.

Other Information:

Store at room temperature (59 °- 86 °F)

Inactive Ingredients:

Water, Lanolin, Mineral Oil, Paraffin, Zinc Oxide, Sorbitan Sequioleate, Beeswax, Propylene Glycol, Imidazolidinyl Urea, Methylparaben, propylparaben, Aluminum Stearate, Phenoxyethanol, Fragrance, Chloroxylenol, Cholecalciferol, Retinyl Palmitate, Aloe Barbadensis Leaf Juice, Tocopheryl Acetate, Zea Mays (corn) Oil

Questions?

Call 1-800-37-6296

Periguard Package Label Principal Display Panel

otc skin protectant drug products ointment

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:61924-205

Route of Administration TOPICAL

Active Ingredient/Active Moiety Ingredient Name Basis of Strength PETROLATUM (UNII: 4T6H12BN9U) (PETROLATUM - UNII:4T6H12BN9U) PETROLATUM (49.9 g in 100 g

Inactive Ingredients				
Ingredient Name	Strength			
ALOE VERA LEAF (UNII: ZY81Z83H0X)				
ALUMINUM STEARATES (UNII: O4D7U3B46U)				
WHITE WAX (UNII: 7G1J5DA97F)				
CORN OIL (UNII: 8470G57WFM)				
CHOLECALCIFEROL (UNII: 1C6V77QF41)				
VITAMIN A PALMITATE (UNII: 1D1K0N0VVC)				
CHLOROXYLENOL (UNII: 0F32U78V2Q)				
IMIDUREA (UNII: M629807ATL)				
METHYLPARABEN (UNII: A2I8C7HI9T)				
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)				
PROPYLPARABEN (UNII: Z8IX2SC1OH)				
LANOLIN (UNII: 7EV65EAW6H)				
MINERAL OIL (UNII: T5L8T28FGP)				
PARAFFIN (UNII: 1900E3H2ZE)				
PHENOXYETHANOL (UNII: HIE492ZZ3T)				
SORBITAN SESQUIOLEATE (UNII: 0W8RRI5W5A)				
.ALPHATOCOPHEROL ACETATE (UNII: 9E8X80D2L0)				
WATER (UNII: 059QF0KO0R)				
ZINC OXIDE (UNII: SOI2LOH54Z)				

	P	Packaging				
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
l	1	NDC:61924-205- 04	100 g in 1 TUBE; Type 0: Not a Combination Product	04/18/2011		
	2	NDC:61924-205- 07	198 g in 1 TUBE; Type 0: Not a Combination Product	04/18/2011		
	3	NDC:61924-205- 05	5 g in 1 PACKET; Type 0: Not a Combination Product	04/18/2011		
	4	NDC:61924-205- 15	15 g in 1 PACKET; Type 0: Not a Combination Product	04/18/2011		
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Marketing Information						
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date			
OTC monograph final	part347	04/18/2011				

Labeler - DermaRite Industries, LLC (883925562)

Revised: 1/2022 DermaRite Industries, LLC