

SMARTH PERISHIELD- zinc oxide ointment
Glint cosmetics Private Limited

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 Facts

Active Ingredient

Zinc Oxide 3.8%

Purpose

Skin Protectant

Uses

■ Helps treat and prevent diaper rash, incontinence or exposure to feces and urine ■ Protects skin against irritation due to such rash and ■ Helps protect skin from exposure to wetness

Warnings

For external use only

When using this product

■ Avoid contact with eyes ■ If eye contact, occurs, flush with water

Stop Use and ask a doctor if

■ condition worsens or doesn't improve within seven days

Keep out of reach of children

If swallowed, get medical help or contact a Poison Control Center right away.

Directions

■ Change wet and soiled diapers promptly ■ Clean diaper area with a mild cleanser, paying special attention to the perineum, buttocks, lower abdomen and inner thighs ■ Allow area to dry ■ Apply to affected area with each diaper change, especially at bedtime or anytime when exposure to soiled diapers may be prolonged

Inactive ingredients

Aloe Barbadensis Gel, Chloroxylenol, Cholecalciferol (Vitamin D3), Zea Mays Oil, Fragrance Lanolin, Mineral Oil, Paraffin, Phenoxyethanol, Retinyl Palmitate (Vitamin A), Sodium Borate, Tocopheryl Acetate (Vitamin E) Water, White Petrolatum

Package Label

SMARTH™

Skin Protectant

- For the Treatment or Prevention of Rash Associated with Diaper Use, Incontinence or Exposure to Feces and Urine
- Forms Protective Barrier to Seal out Wetness
- Zinc Oxide

Dermatologist Tested

Reorder #: 500
3.5 OZ. (100 GRAMS)

Patient Name:

Skin Protectant

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 ■ Protects skin against irritation due to such rash and
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FOR EXTERNAL USE ONLY

When using this product ■ Avoid contact with eyes
 ■ If eye contact occurs, flush with water

Stop use and ask a doctor if
 ■ condition worsens or doesn't improve within seven days

Keep out of reach of children If swallowed, get medical help or contact a Poison Control Center right away.

Directions
 ■ Change wet or soiled diapers promptly
 ■ Clean diaper area with a mild cleanser, paying special attention to the perineum, buttocks, lower abdomen and inner thighs
 ■ Allow area to dry
 ■ Apply to affected area as often as necessary or with each diaper change, especially at bedtime or any time when exposure to soiled diapers may be prolonged

Inactive Ingredients Aloe Barbadensis Gel, Chloroxylenol, Chloecalciferol (Vitamin D3), Zea Mays Oil, Fragrance, Lanolin, Mineral Oil, Paraffin, Phenoxyethanol, Retinyl Palmitate (Vitamin A), Sodium Borate, Tocopheryl Acetate (Vitamin E), Water, White Petrolatum

Manufactured By:
Glint Cosmetics Pvt. Ltd.,
C-216-217-218, TTC Indl. Area, M.I.D.C.,
Turbhe, Navi Mumbai-400 705.
Made in India



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SMARTH PERISHIELD

zinc oxide ointment

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71486-8020
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name		Basis of Strength	Strength	
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)		ZINC OXIDE	3.8 g in 100 g	
Inactive Ingredients				
Ingredient Name		Strength		
ALOE VERA LEAF (UNII: ZY81Z83H0X)				
CHLOROXYLENOL (UNII: 0F32U78V2Q)				
CHOLECALCIFEROL (UNII: 1C6V77QF41)				
CORN OIL (UNII: 8470G57WFM)				
LANOLIN (UNII: 7EV65EAW6H)				
MINERAL OIL (UNII: T5L8T28FGP)				
PARAFFIN (UNII: I9O0E3H2ZE)				
PHENOXYETHANOL (UNII: HIE492ZZ3T)				
VITAMIN A PALMITATE (UNII: 1D1K0N0VVC)				
SODIUM BORATE (UNII: 91MBZ8H3QO)				
ALPHA-TOCOPHEROL (UNII: H4N855PNZ1)				
WATER (UNII: 059QF0K00R)				
PETROLATUM (UNII: 4T6H12BN9U)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71486-8020-4	452 g in 1 JAR; Type 0: Not a Combination Product	01/01/2015	
2	NDC:71486-8020-0	100 g in 1 TUBE; Type 0: Not a Combination Product	01/01/2015	
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph final	part347	01/01/2015		

Labeler - Glint cosmetics Private Limited (675910492)

Establishment

Name	Address	ID/FEI	Business Operations
GLINT COSMETICS PRIVATE LIMITED		675910492	manufacture(71486-8020)

Revised: 11/2018

Glint cosmetics Private Limited