GLINT- 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.

Glint Zinc Oxide

Active Ingredient

Zinc Oxide 20% w/w

Purpose

Diaper Rash Cream

Uses

■ helps treat and prevent diaper rash ■ dries the oozing and weeping of ■ poison ivy ■ poison oak ■ poison sumac

Warnings

For external use only

When using this product

- do not get into eyes
- do not use over large areas of the body

Stop use and ask a doctor if

■ the condition worsens ■ symptoms last more than 7 days or clear up and occur again in a few days ■ if you are allergic to any of these ingredients

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

Directions

■ for diaper rash ■ change wet and soiled diapers promptly ■ cleanse the diaper area and allow to dry ■ apply ointment liberally with each diaper change, especially at bedtime or anytime when exposure to wet diapers may be prolonged ■ for poison ivy, oak sumac ■ apply ointment liberally as often as needed

Other Information

■ store at 59-86F (15-30C)

Inactive Ingredients

cetostearyl alcohol, cetomacrogol 1000, light liquid paraffin, white soft parrafin

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Struct Zinc Oxide Ointment SKIN PROTECTANT	
Net Wt. SKIN PROTECTANT	
Drug Facts Active ingredient Purpose Zeco Oxide Streat and provent dispert Zeco Oxide Streat and provent dispert Bese in holps treat and provent dispert Secondation and weeping of a poisson lay a lay and lay a doctor if a his body lay and lay and lay a doctor lay a l	

GLINT						
zinc oxide ointment						
Product Informa	tion					
Product T ype		HUMAN OTC DRUG	Item Code (S	ource)	NDC:71	486-3040
Route of Administr	ation	TOPICAL				
Active Ingredier	t/Active Moi	ety				
Ingredient Name		Basis of Stre	Basis of Strength			
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z) ZINC OXIDE					20 g in 100 g	
Inactive Ingredi	nte					
mactive ingreun		Ingredient Name				Strength
CETOSTEARYL ALC	C OHOL (UNII: 2E	<u> </u>				
CETETH-20 (UNII: 1835H2IHHX)						
LIGHT MINERAL OIL (UNII: N6K5787QVP)						
PETROLATUM (UNII: 4T6H12BN9U)						
Packaging				- Hand Chant Date	Maxl	ating End Dat
Packaging # Item Code		Package Description	Mark	eting Start Date	WIGTK	eting End Date
		Package Description ; Type 0: Not a Combination Pro		0	Mark	eting End Date

Marketing Information							
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date				
OTC monograph final	part347	09/17/2018					

Labeler - GLINT COSMETICS PRIVATE LIMITED (675910492)

Revised: 9/2018

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