

GLINT- hydrocortisone cream
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

Hydrocortisone Acetate USP (1% w/w)

Purpose

Anti-itch

Uses

■ for temporary relief of minor skin irritations, itching and rashes due to eczema, insect bites, poison ivy, poison oak, poison sumac, soaps, detergents, cosmetics, jewelry, and for external genital, feminine and anal itching. Other uses of this product should be only under the advice and supervision of a doctor

Warnings

For external use only

Do not use

■ in the eyes ■ for diaper rash ■ if you have vaginal discharge ■ more than the recommended dosage

Ask a doctor before use

■ if you are pregnant or breast feeding

Stop use and ask a doctor if

■ the condition worsens, or if symptoms persist for more than 7 days or clear up and occur again within a few days

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

Directions

- adults and children over 2 years of age
- apply evenly to affected area no more than 3 to 4 times daily
- children under 2 years of age
- do not use, consult a doctor
- adults and children over 2 years of age
- apply evenly to affected area no more than 3 to 4 times daily

- children under 2 years of age
- do not use, consult a doctor
- **Adults**
- when practical, cleanse the affected area with mild soap and warm water and rinse thoroughly
- gently dry, patting or blotting with bathroom tissue or soft cloth before applying
- apply externally to the area up to 6 times a daily or after a bowel movement
- after application discard pad
- do not flush in toilet

Other information

- store at 20-25C (68-77F)
- avoid excessive heat and humidity

Inactive Ingredients

cetostearyl alcohol, chlorocresol, ceteth-20, edetate disodium, liquid paraffin, propylene glycol, purified water, sodium metabisulphite, White white soft paraffin

Net Wt. 1 oz (28.3g)

Hydrocortisone Cream 1% ANTI-ITCH CREAM

Relief of Minor Skin Irritation Itching & Rashes

Reorder No: MPR-30503

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<p>Drug Facts</p> <p>Active ingredients Hydrocortisone Acetate USP (1% w/w).....</p> <p>Purpose Anti-Itch</p> <p>Uses ■ for temporary relief of minor skin irritations, itching and rashes due to eczema, insect bites, poison ivy, poison sumac, poison oak, soaps, detergents, cosmetics, jewelry, and for external genital, feminine and anal itching. Other uses of this product should be only under the advice and supervision of a doctor. ▶</p>	<p>Drug Facts (continued)</p> <p>Warnings: FOR EXTERNAL USE ONLY</p> <p>Do not use ■ in the eyes ■ for diaper rash ■ if you have vaginal discharge ■ more than the recommended dosage</p> <p>Ask a doctor before use if ■ if you are pregnant or breast-feeding</p> <p>Stop use and ask a doctor if ■ the condition worsens, or if symptoms persist for more than 7 days or clear up and occur again within a few days ▼</p>
<p>Drug Facts (continued)</p> <p>Keep out of reach of children ■ If swallowed, get medical help or contact a Poison Control Center right away</p> <p>Directions For itching of skin irritation, inflammation and rashes: ■ adults and children over 2 years of age ■ apply evenly to affected area no more than 3 to 4 times daily ■ children under 2 years of age ■ do not use, consult a doctor For external anal and genital itching, adults: ■ when practical, cleanse the affected area with mild soap and warm water and rinse thoroughly ■ gently dry, patting or blotting with bathroom tissue or soft cloth before applying ■ apply externally to the area up to 6 times daily or after each bowel movement ■ after application, discard pad ■ do not flush in toilet ▶</p>	<p>Drug Facts (continued)</p> <p>Other Information ■ store at room temperature 68°-77°F (20°-25°C) ■ avoid excessive heat and humidity</p> <p>Inactive Ingredients cetostearyl alcohol, chlorocresol, ceteth-20, edetate disodium, liquid paraffin, propylene glycol, purified water, sodium metabisulphate, white soft paraffin</p> <p><small>Manufactured For: Glint Cosmetics Pvt. Ltd., C-216-217-218, TTC Indl. Area, M.D.C., Turbhe, Navi Mumbai-400 705 Made in India</small></p>

LOT:
EXP:
MFG DATE:

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71486-3050
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
HYDROCORTISONE ACETATE (UNII: 3X7931PO74) (HYDROCORTISONE - UNII:WI4X0X7BPJ)	HYDROCORTISONE ACETATE	10 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
CETOSTEARYL ALCOHOL (UNII: 2DMT128MIS)	
CHLOROCRESOL (UNII: 36W53O7109)	
CETETH-20 (UNII: I835H2IHHX)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
MINERAL OIL (UNII: T5L8T28FGP)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SODIUM METABISULFITE (UNII: 4VON5FNS3C)	
PETROLATUM (UNII: 4T6H12BN9U)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71486-3050-2	0.9 g in 1 PACKET; Type 0: Not a Combination Product	05/23/2013	
2	NDC:71486-3050-3	28.3 g in 1 TUBE; Type 0: Not a Combination Product	05/23/2013	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	05/23/2013	

Labeler - GLINT COSMETICS PRIVATE LIMITED (675910492)**Establishment**

Name	Address	ID/FEI	Business Operations
GLINT COSMETICS PRIVATE LIMITED		675910492	manufacture(71486-3050)