

LINCOLN- hydrocortisone acetate cream
Lincoln Pharmaceuticals Ltd.

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

Hydrocortisone Acetate USP (1 % W/W)

Drug Facts

Anti-Itch

Drug Facts

for external use only

USES

- For temporary relief of minor skin irritations, itching and rashes due to eczema, insect bites, poison ivy position 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

Drug Facts

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

Drug Facts

If you are pregnant or breast- feeding

Drug Facts

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

Drug Facts

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

Drug facts

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 upto 6 times daily or after each bowel movement
- after application, discard pad
- do not flush in toilet

Drug Facts

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

Drug Facts:

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

Package Label



Net Wt.
1 oz (28.3g)

Hydrocortisone Cream 1%

ANTI-ITCH CREAM

NDC: 69636-3050-3



Drug Facts		Drug Facts (continued)	
Active ingredients Hydrocortisone Acetate USP (1% w/w).....	Purpose Anti-Itch	Warnings: FOR EXTERNAL USE ONLY	
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. ▶		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 ■ 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 ▼	
Drug Facts (continued)		Drug Facts (continued)	
Keep out of reach of children ■ If swallowed, get medical help or contact a Poison Control Center right away		Other Information ■ store at room temperature 68°-77°F (20°-25°C) ■ avoid excessive heat and humidity	
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 ▶		Inactive Ingredients cetostearyl alcohol, chlorocresol, ceteth-20, edetate disodium, liquid paraffin, propylene glycol, purified water, sodium metabisulphate, white soft paraffin	

LINCOLN

hydrocortisone acetate cream

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69636-3050
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
HYDROCORTISONE ACETATE (UNII: 3X7931PO74) (HYDROCORTISONE - UNII:WI4X0X7BPJ)	HYDROCORTISONE ACETATE	0.01 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
CHLOROCRESOL (UNII: 36W53O7109)	
CETETH-20 (UNII: I835H2IHHX)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
MINERAL OIL (UNII: T5L8T28FGP)	
PROPYLENE GLYCOL 1,2-DISTEARATE (UNII: T65PN3O37H)	
WATER (UNII: 059QF0KO0R)	
SODIUM METABISULFITE (UNII: 4VON5FNS3C)	
PETROLATUM (UNII: 4T6H12BN9U)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69636-3050-2	0.9 g in 1 PACKET; Type 0: Not a Combination Product	05/23/2013	
2	NDC:69636-3050-3	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 - Lincoln Pharmaceuticals Ltd. (915839373)**Establishment**

Name	Address	ID/FEI	Business Operations
Lincoln Pharmaceuticals Ltd.		915839373	manufacture(69636-3050)

Revised: 4/2016

Lincoln Pharmaceuticals Ltd.