MAKESENSE MAXIMUM STRENGTH- hydrocortisone cream Cherry Hill Sales Co

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 1%

Purpose

Anti-itch

Uses

■ for temporary relief of itching associated with minor skin irritations and rashes due to: ■ eczema seborrheic dermatitis ■ psoriasis ■insect bites ■ poison ivy, oak, sumac ■ soaps ■ detergents ■ cosmetics ■ jewelry ■ temporarily relieves external anal and genital itching ■ other uses of this product should be under the advice and supervision of a doctor

Warnings

For external use only

Do not use

■ in the genital area if you have vaginal discharge. Consult a doctor ■ for the treatment of diaper rash. Consult a doctor

When using this product

■ avoid contact with eyes ■ do not use more than directed unless told to do so by a doctor ■ do not put directly into the rectum by using fingers or any mechanical device or applicator

Stop use and ask a doctor if

■ the condition worsens, symptoms persist for more than 7 days or clear up and occur again wihin a few days, and do not beginuse of any other hydrocortisone product unless you have asked a doctor ■ rectal bleed occurs

Keep out of reach of children

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

Directions

■ **for itching of skin irritation and rashes:** ■ adults and children 2 years of age and older: apply to affected area not more than 3 to 4 times daily ■ children under 2 years of age: ask a doctor

for external anal and genital itching: adults: ■ when practical, clean the affected area with mild soap and water and rinse thoroughly ■ gently dry by patting or blotting with toilet tissue or a soft cloth before applying ■ apply to affected area not more than 3 to 4 times daily ■ children under 12 years of age: ask a doctor

Other information

■ store at 68-77F (20 to 25C) ■ see carton or tube crimp for lot number and expiration date

Inactive Ingredients

Cetearyl Alcohol, Disodium EDTA, Glyceryl Stearate, Methylparaben, Mineral Oil, Petrolatum, Polysorbate 60, Propylene Glycol, Propylparaben, Sorbitan Stearate, Water

Package Label



MAKESENSE MAXIMUM STRENGTH

hydrocortisone cream

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69020-204	
Route of Administration	TOPICAL			

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
HYDRO CO RTISO NE (UNII: WI4X0 X7BPJ) (HYDRO CO RTISO NE - UNII: WI4X0 X7BPJ)	HYDROCORTISONE	1 g in 100 g	

Inactive Ingredients		
Ingredient Name	Strength	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)		
EDETATE DISO DIUM (UNII: 7FLD9 1C86K)		
GLYCERYL STEARATE SE (UNII: FCZ5MH785I)		
METHYLPARABEN (UNII: A2I8 C7HI9 T)		
MINERAL OIL (UNII: T5L8T28FGP)		
PETROLATUM (UNII: 4T6H12BN9U)		
POLYSORBATE 60 (UNII: CAL22UVI4M)		
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)		
PROPYLPARABEN (UNII: Z8IX2SC1OH)		
SORBITAN MONOSTEARATE (UNII: NVZ4I0H58X)		
WATER (UNII: 059QF0KO0R)		

F	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:69020-204-14	14 g in 1 TUBE; Type 0: Not a Combination Product	06/15/2014		

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part348	06/15/2014		

Labeler - Cherry Hill Sales Co (145959768)

Revised: 8/2016 Cherry Hill Sales Co