HYDROCORTISONE- hydrocortisone cream
UniShield

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.

HYDROCORTISONE CREAM

Drug Facts

Warnings

For external use only

Do not use
- in eyes
- for treatment of diaper rash

Stop use, as a doctor
- if condition worsens or lasts more than 7 days, or clears up and occurs again within a few days
- with use of other hydrocortisone products

Keep out of reach of children.

If ingested, contact a Poison Control Center right away

Directions
- apply to affected area not more than 3 to 4 times daily
- children under 2: ask a doctor

Inactive ingredients

Emulsifying wax, ethanol, methylparaben, mineral oil, paraffin, petrolatum, propylparaben, purified water, white wax

ACTIVE INGREDIENT

Hydrocortisone 1.0%

USES:

For temporary relief of itching associated with minor skin irritations, inflammation or rashes. Other uses of product should be only under the advice and supervision of a doctor.

PRINCIPLE DISPLAY PANEL

HYDROCORTISONE CREAM

1/32 oz. (0.9g)

Dist by:**UniShield**

San Fernando, CA 91340

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HYDROCORTISONE

hydrocortisone cream

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:49314-5801
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
Hydrocortisone (UNII: WI4X0X7BPJ) (Hydrocortisone - UNII:WI4X0X7BPJ)	Hydrocortisone	10 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
alcohol (UNII: 3K9958V90M)	
methylparaben (UNII: A2I8C7HI9T)	
mineral oil (UNII: T5L8T28FGP)	
paraffin (UNII: I9O0E3H2ZE)	
petrolatum (UNII: 4T6H12BN9U)	
propylparaben (UNII: Z8IX2SC1OH)	
water (UNII: 059QF0KO0R)	
cetostearyl alcohol (UNII: 2DMT128M1S)	
polysorbate 60 (UNII: CAL22UVI4M)	
PEG-150 distearate (UNII: 6F36Q0I0AC)	
steareth-20 (UNII: L0Q8IK9E08)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49314-5801-0	0.8 mL in 1 PACKET		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part348	07/28/2010	

Labeler - UniShield (790677053)

Registrant - Safetec of America, Inc. (874965262)

Establishment

Name	Address	ID/FEI	Business Operations
Safetec of America, Inc.		874965262	MANUFACTURE

Revised: 7/2010 UniShield