ANTI-ITCH- hydrocortisone cream
Welly Health PCB

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 1.0%

Purpose

Anti-itch

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.

Warnings

External use only

Do not use

- in eyes
- for treatment of diaper rash
- for feminine itching

Stop use, ask a doctor

- if conditions worsen 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

Welly Health PBC, Minn., MN 55402

1-833-BE-WELLY

Principal Display Panel - Welly Health Hydrocortisone Cream Pouch Label

Welly™

1% Hydrocortisone
Cream

0.9g/ 1/32 OZ

ANTI-ITCH

hydrocortisone cream

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:72663-580
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
hydrocortisone (UNII: WI4X0X7BPJ) (hydrocortisone - UNII:WI4X0X7BPJ)	hydrocortisone	1 g 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)	
white wax (UNII: 7G1J5DA97F)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72663-580-02	0.9 mL in 1 POUCH; Type 0: Not a Combination Product	02/25/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	02/25/2019	

Labeler - Welly Health PCB (116766884)

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