HYDROCORTISONE- hydrocortisone cream
Kareway Product, Inc.

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.

Soundbody Hydrocortisone

Active Ingredient

Hydrocortisone 1%

Purpose

Anti-itch

Uses

temporarily relieves itching associated with minor sin irritation, inflammation and rashes due to:

- eczema
- insect bites
- poison ivy, oak, sumac
- soaps
- detergents
- cosmetics
- jewelry
- seborrheic dermatitis
- psoriasis
- temporarily relieves external anal and genital itching
- other uses of this product should only be under the advice and supervision of a doctor

Warnings

For external use only.

Do not use

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

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Stop use and ask a doctor if

- condition worsens, symptoms persist for more than 7 days or clear up and occur again within a few days, and do not begin us of any other hydrocortisone product unless you have asked a doctor
- rectal bleeding 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, inflammation, 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: 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 20 to 25 ºC (68 to 77 ºF)
- see end of carton or tube crimp for lot number and expiration date

butylated hydroxytoluene, carbomer 940, cetyl alcohol, ethylparaben, glycerin, glyceryl stearate, propylene glycol, sodium lauryl sulfate, stearic acid, trolamine, water

Hydrocortisone

HYDROCORTISONE

hydrocortisone cream

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:67510-0632
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
HYDROCORTISONE (UNII: W4X0X7BPJ) (HYDROCORTISONE - UNII:W4X0X7BPJ)	HYDROCORTISONE	1 g in 100 g

Inactive Ingredients	
Ingredient Name	**Strength**
TROLAMINE (UNII: 9O3K93S3TK)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
ETHYLPARABEN (UNII: 14255EXE39)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
GLYCERIN (UNII: PDC6A3C0OX)	
CARBOMER 940 (UNII: 4Q93RCW27E)	
GLYCERYL 1-STEARATE (UNII: 258491E1RZ)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
WATER (UNII: 059QF0KO0R)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:67510-0632-1	1 in 1 BOX	12/12/2013	
1		28.3 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	12/12/2013	

Labeler - Kareway Product, Inc. (121840057)

Revised: 1/2023 Kareway Product, Inc.