

**SOFSKIN HYDROCORTISONE 1 PERCENT- hydrocortisone hcl cream
GOPALDAS VISRAM AND COMPANY LIMITED**

Gopaldas (as CMO) - SOFSKIN HYDROCORTISONE CREAM 1% (61040-129)

ACTIVE INGREDIENTS

HYDROCORTISONE 1%

PURPOSE

Antipruritic (Anti-Itch)

USES

- temporarily relieves itching associated with minor skin irritations, inflammation, and rashes due to:
- eczema
- psoriasis
- poison ivy
- poison oak
- poison sumac
- insect bites
- detergents
- jewelry
- cosmetics
- soaps
- seborrheic dermatitis
- 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. 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

- condition worsens, symptoms persist for more than 7 days or clear up and occur again within a few days, and do not begin use 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 (1-800-222-1222) right away.

DIRECTIONS

- for itching or 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 of age: ask a doctor
- for external anal and genital itching, adults:
- when practical, clean the affected area with mild soap and warm 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

- do not use if seal on the tube is damaged or is not visible
- to open, unscrew cap, pull tab to remove foil seal
- store at 20° to 25°C (68° to 77°F)
- avoid excessive heat and humidity
- see crimp of tube or carton for Lot Number and Expiry Date

INACTIVE INGREDIENT

Aloe Vera Extract, Cetostearyl Alcohol, Glyceryl Monostearate SE, Kathon CG, Propylene Glycol, Purified Water, Stearic Acid, Trolamine, White Petrolatum

NDC 00000-0000-00

Compare to the active ingredient in Cortizone-10®



Hydrocortisone 1% Cream

Anti - Itch Cream

Net Wt. 1 oz (28.4 g)

Drug Facts	
Active ingredient Hydrocortisone 1%	Purpose Antipruritic (Anti-Itch)
Use(s) temporarily relieves itching associated with minor skin irritations, inflammation, and rashes due to: ■ eczema ■ psoriasis ■ poison ivy ■ poison oak ■ poison sumac ■ insect bites ■ detergents ■ jewelry ■ cosmetics ■ soaps ■ seborrheic dermatitis ■ 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. 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.	
Drug Facts (Continued)	
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 use 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 (1-800-222-1222) right away.	
Other information ■ do not use if seal on the tube is damaged or is not visible. To open, unscrew cap, pull tab to remove foil seal ■ store at room temperature 20°-25°C (68-77°F) ■ see crimp of tube or carton for Lot Number and Expiry Date	
Inactive ingredients Aloe Vera Extract, Cetostearyl Alcohol, Glyceryl Monostearate SE, Kathon CG, Propylene Glycol, Purified Water, Stearic Acid, Trolamine, White Petrolatum	
Questions? Call	
See box for complete Drug Facts	

*This product is not affiliated with, manufactured by, or produced by the makers or owners of Cortizone-10®

MH/DRUGS/28-KD/503

Made in India

Exclusively distributed by:
Viny Health and Beauty Products Inc, New York, USA
www.viny.us

BARCODE



Hydrocortisone 1% Cream

Anti - Itch Cream

NDC 00000-0000-00

Compare to the active ingredient in Cortizone-10®

Hydrocortisone 1% Cream

Anti - Itch Cream

Net Wt. 1 oz (28.4 g)

Hydrocortisone
1% Cream
Anti - Itch Cream

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Hydrocortisone 1% Cream
Anti - Itch Cream



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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 use of any other hydrocortisone		Inactive Ingredients Aloe Vera Extract, Cetostearyl Alcohol, glyceryl Monostearate oil, Kathon CB, Propylene glycol, Purified Water, stearic Acid, Trolamine, White Petrolatum	
		Question or comments? Call:	

SOFSKIN HYDROCORTISONE 1 PERCENT

hydrocortisone hcl cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:61040-129
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
HYDROCORTISONE (UNII: W4X0X7BP) (HYDROCORTISONE - UNII:W4X0X7BP)	HYDROCORTISONE	1 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
WHITE PETROLATUM (UNII: B6E5W8RQJ4)	
GLYCERYL STEARATE SE (UNII: FCZ5MH785I)	
WATER (UNII: 059QF0KO0R)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TROLAMINE (UNII: 9O3K93S3TK)	
METHYLCHLOROISOTHIAZOLINONE/METHYLISOTHIAZOLINONE MIXTURE (UNII: 15O9QS218W)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61040-129-11	1 in 1 BOX	07/15/2024	
1	NDC:61040-129-	28.4 g in 1 TUBE; Type 0: Not a Combination		

01	Product		
Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M016	07/15/2024	

Labeler - GOPALDAS VISRAM AND COMPANY LIMITED (858030888)

Revised: 12/2024

GOPALDAS VISRAM AND COMPANY LIMITED