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



Net Wt. 1 oz (28.4 g)

Drug Facts Active ingredient Hydrocortisone 1% Antipruritic (Anti-Itch)	Drug Facts (Continued) Stop use and ask a doctor if a 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 arectal	*This product is not affiliated with, manfactured by, or produced by the makers or owners of Cortizone-10*	
Use(s) memorarity relieves itching associated with minor skin initiations, inflammation, and rashes due to: mecrema mesoriasis megoioson by mepoison oak metoison sumac mentatisme delergents metoises delergents and genital seares metoises sectoratismetoriatismetoria procession and genital	bleeding occurs Keep eut of reach of children. If swallowed, get medical help or contact a Poison Control Center (1-800-222-1222) right away.	MH/DRUGS/28-KD/503 Made in India	
Iching other uses of this product should only be under the advice and supervision of 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 room temperature 20°-25°C (68-77°F) ■ see crimp of tube or caron to for Lot Number and Expiry Date	Exclusively distributed by: Viny Health and Beauty Products Inc, New York, USA	
Warnings For external use only Do not use in the genital area if you have a vaginal discharge. Consult a joctor, in for the freatment of diaper rash. Consult a doctor.	Inactive ingredients Aloe Vera Extract, Cetostearyl Alcohol, Glyceryl Monoslearate SE, Kathon CG,	www.viny.us	
When using this product a avoid contact with eyes a do not use more than firected unless told to do so by a doctor a do not put directly into the rectum y using fingers or any mechanical device or applicator.	Propylene Glycol, Purified Water, Stearic Acid, Trolamine, White Petrolatum Questions? Call See box for complete Drug Facts	BARCODE	



Hydrocortisone 1 % Cream Anti - Itch Cream

MHDRUosite-KDig03 Made in India Exclusively distributed by: Vitry Health and Beauly Products Inc, New York, UsA BARCODE Mode in India

Hydrocortisone 1 % Cream Anti - Itch Cream	Sofskin		
Drug Facts	Drug Facts (Continued)		
Active ingredient Purpose Hydrocrisore 1%	product unless you have asked a doctor precial bleeding occurs		
Use(s) temporarily releves liching associated with minor skin initiations, inflammation,	Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center (1-600-222-1222) right away.		
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again within a few days, and do not begin use of any other hydrocortisone	Question or comments? Cal-		

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Ρ	roduct Infor	mation					
Ρ	roduct Type		HUMAN OTC DRUG	Item Code (Source) NDC:61040-129			040-129
R	oute of Admini	stration	TOPICAL				
A	ctive Ingredi	ent/Active	Moiety				
	Ingredient Name Basis of Strengt				trength	Strength	
H١	YDROCORTISONI	E (UNII: WI4X0X	7BPJ) (HYDROCORTISONE -	UNII:W4X0X7BPJ)	HYDROCORTIS	SONE	1 g in 100 g
Ir	nactive Ingre	dients	Ingredient Nan	ıe			Strengt
	J		Ingredient Nan	ne			Strengt
C	ETOSTEARYL ALC	COHOL (UNII: 2	DMT128M1S)				
AL	OE VERA LEAF (UNII: ZY81Z831	HOX)				
	HITE PETROLAT						
	LYCERYL STEARA		CZ 5MH785I)				
	ATER (UNII: 059Q	•					
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			ONE/METHYLISOTHIAZOI	INONE MIXTURE		218\\\\\\	
	ROPYLENE GLYC				(01111: 1505032	1010	
P	ackaging						
#	ltem Code	Ра	ckage Description		ing Start ate		eting End Date
1	NDC:61040-129- 11	1 in 1 BOX		07/15/2024			

1 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