VANICREAM HC ANTI-ITCH- hydrocortisone cream Pharmaceutical Specialties, Inc.

VANICREAM™ HC Anti-Itch Cream

Drug Facts

Active ingredient

Hydrocortisone acetate 1.12%

(equivalent to hydrocortisone 1%)

Purpose

Anti-itch

Uses

- for the temporary relief of itching associated with minor skin irritations, inflammation and rashes due to:
- · eczema · psoriasis · insect bites
- · detergents · jewelry · seborrheic dermatitis
- · soaps · cosmetics · poison ivy, oak, sumac
- for the temporary relief of external genital and anal itching
- other uses of this product should be only 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 the eyes
- do not exceed the recommended daily dosage unless directed by a doctor
- do not put this product into the rectum by using fingers or any mechanical device or applicator

Stop use and ask a doctor if

- condition worsens
- rectal bleeding occurs
- 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 consulted a doctor.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away

Directions

- for itching due to minor skin irritations, 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: Do not use, consult a doctor.
- for external anal and genital itching, adults:
- when practical, cleanse 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 application of this product
- apply to affected area not more than 3 to 4 times daily
- children under 12 years of age: consult a doctor

Other information

store at room temperature

Inactive ingredients ceteareth-20, cetearyl alcohol, glyceryl stearate, PEG-30 stearate, petrolatum, propanediol, purified water, simethicone, sorbic acid, sorbitol

Questions?

1-800-325-8232

www.vanicream.com

*To learn more about our products and ingredients, visit www.vanicream.com or call 1-800-325-8232

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PHARMACEUTICAL SPECIALTIES, INC.

ROCHESTER, MN 55901

Made in U.S.A.

GP210

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NDC 45334-327-02

DERMATOLOGIST TESTED

MAXIMUM STRENGTH

VANICREAM™ HC

1% Hydrocortisone Anti-Itch Cream

for Sensitive Skin

Free of dyes, fragrance, masking fragrance, lanolin, parabens & formaldehyde releasers

Non-comedogenic ● Gluten-Free

Fast relief for flare-ups due to

- eczema
- dermatitis
- psoriasis

Net Wt 2 oz (57 g)

VANICREAM*HC

1% Hydrocortisone Anti-Itch Cream



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To learn more about our products and ingredients, visit www.varilcream.com or call 1-800-825-8232.

FIS Official Vanicream

PHARMACEUTICAL SPECIALTIES, INC.,

MAXIMUM STRENGTH

1% Hydrocortisone Anti-Itch Cream

Fast relief for flare-ups due to

NDC 45334-327-02 DERMATOLOGIST TESTED



dermatitis

eczema

THE MOST IMPORTANT INGREDIENT IS TRUST"

Vanicream™ HC 1% Hydrocorlisone Anti-Itch Cream is created for those who need want to avoid common chemical irritants found in ordinary skin care products.

This sensitive skin formula provides effective relief from itching associated with minor skin irritations, inflammation and rashes due to: jewelry
 detergents
 insect bites soaps
cosmetics
poison ivy, oak or sumac

eczemaseborrheic dermatitispsoriasis

VANICREAM HC ANTI-ITCH

hydrocortisone cream

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:45334-327

Route of Administration TOPICAL

Active Ingredient/Active Moiety Ingredient Name Basis of Strength HYDROCORTISONE ACETATE (UNII: 3X7931PO74) (HYDROCORTISONE UNII:W4X0X7BPJ) HYDROCORTISONE ACETATE In 100 g

Inactive Ingredients				
Ingredient Name	Strength			
PETROLATUM (UNII: 4T6H12BN9U)				
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)				
SORBIC ACID (UNII: X045WJ989B)				
POLYOXYL 20 CETOSTEARYL ETHER (UNII: YRC528SWUY)				
PEG-30 STEARATE (UNII: 1U8KB35S20)				
PROPANEDIOL (UNII: 5965N8W85T)				
SORBITOL (UNII: 506T60A25R)				
GLYCERYL MONOSTEARATE (UNII: 2300U9XXE4)				
WATER (UNII: 059QF0KO0R)				
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)				
DIMETHICONE (UNII: 92RU3N3Y10)				

Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:45334-327- 02	1 in 1 CARTON	01/26/2016		
1		57 g in 1 TUBE; Type 0: Not a Combination Product			
2	NDC:45334-327- 04	4 g in 1 TUBE; Type 0: Not a Combination Product	02/09/2016	01/31/2024	

Marketing Information					
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
OTC Monograph Drug	M017	01/26/2016			

Establishment						
Name	Address	ID/FEI	Business Operations			
Pharmaceutical Specialties, Inc.		076499557	manufacture(45334-327), pack(45334-327), label(45334-327)			

Revised: 10/2023 Pharmaceutical Specialties, Inc.