

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 cetareth-20, cetaryl alcohol, glyceryl stearate, PEG-30 stearate, petrolatum, propanediol, simethicone, sorbic acid, sorbitol, water

Questions?

1-800-325-8232

www.vanicream.com

*To learn more about our products and ingredients, visit www.vanicream.com

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PHARMACEUTICAL SPECIALTIES, INC.

ROCHESTER, MN 55901

1-800-325-8232

Made in USA with select US and imported materials

GP24H

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NDC 45334-327-02

DERMATOLOGIST TESTED

MAXIMUM STRENGTH

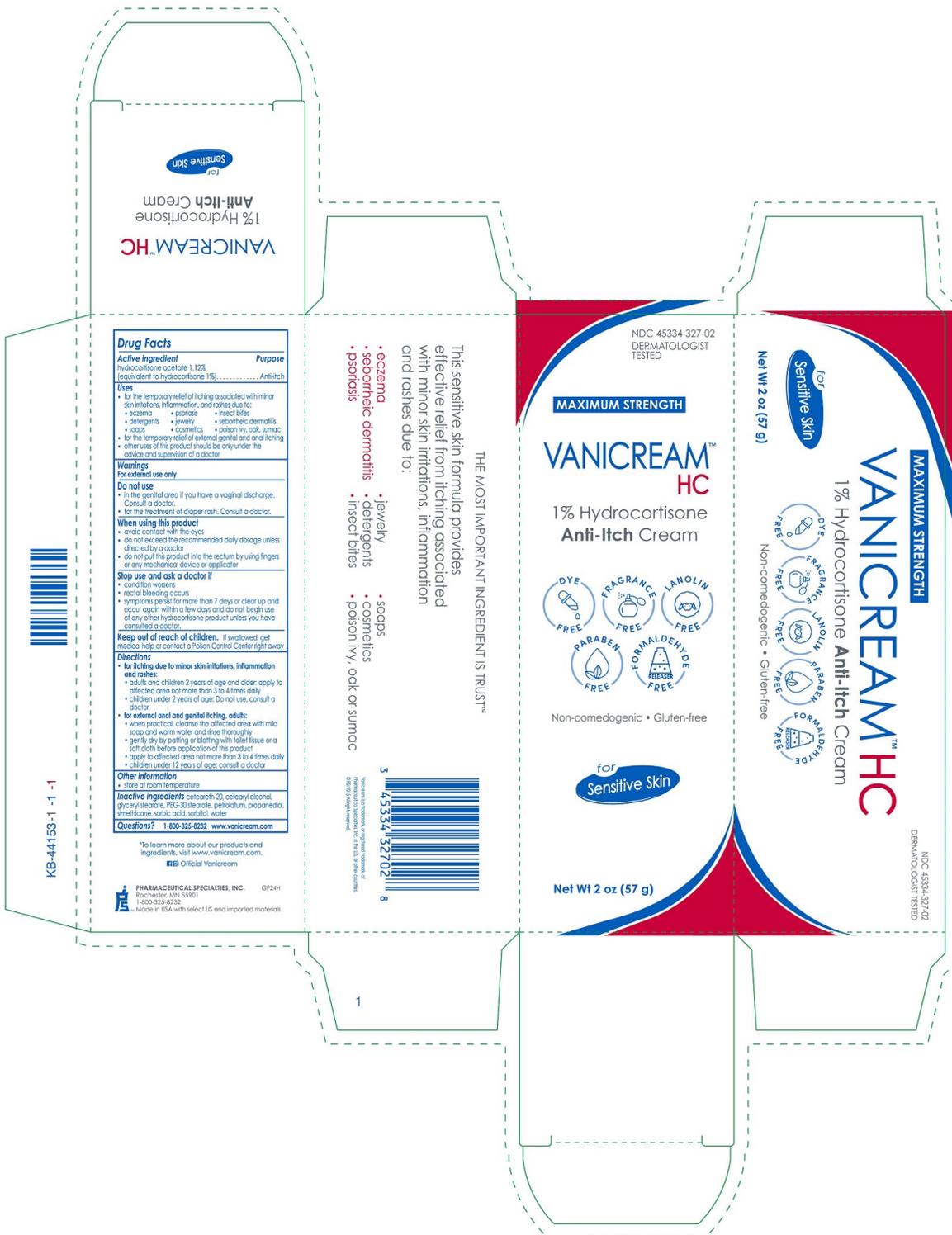
VANICREAM™ HC

1% Hydrocortisone Anti-Itch Cream

Non-comedogenic ● Gluten-Free

for Sensitive Kin

Net Wt 2 oz (57 g)



for Sensitive Skin
VANICREAMTM HC
 1% Hydrocortisone
 Anti-Itch Cream

Drug Facts
Active Ingredient Purpose
 Hydrocortisone acetate 1.12% (equivalent to hydrocortisone 1%) 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 cetylalcohol, cetylalcohol, glyceryl linoleate, PEG-30 dipalmitate, petrolatum, propylene glycol, stearic acid, sorbitol, water

Questions? 1-800-325-8232 www.vanicream.com

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 Rochester, MN 55901
 1-800-325-8232
 Made in USA with select US and imported materials

THE MOST IMPORTANT INGREDIENT IS TRUST™
 This sensitive skin formula provides effective relief from itching associated with minor skin irritations, inflammation and rashes due to:

- eczema
- seborrheic dermatitis
- psoriasis
- jewelry
- detergents
- insect bites
- soaps
- cosmetics
- poison ivy, oak or sumac



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MAXIMUM STRENGTH
VANICREAMTM HC
 1% Hydrocortisone
 Anti-Itch Cream



Non-comedogenic • Gluten-free

for Sensitive Skin

Net Wt 2 oz (57 g)

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for Sensitive Skin
MAXIMUM STRENGTH
VANICREAMTM HC
 1% Hydrocortisone
 Anti-Itch Cream



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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	Strength
HYDROCORTISONE ACETATE (UNII: 3X7931PO74) (HYDROCORTISONE - UNII:W4X0X7BPJ)	HYDROCORTISONE ACETATE	1.12 g 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: 230OU9XXE4)	
WATER (UNII: 059QF0KO0R)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
DIMETHICONE (UNII: 92RU3N3Y1O)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:45334-327-02	1 in 1 CARTON	01/26/2016	11/25/2026
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	11/25/2026

Labeler - Pharmaceutical Specialties, Inc. (076499557)

Establishment

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

