

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)



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	
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	

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)

