

HYDROCORTISONE- hydrocortisone cream
Safetec of America, Inc.

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Drug Facts

Active Ingredients

Hydrocortisone USP 1%

Purpose

Antipruritic (Anti-itch)

Uses

For the temporary relief of itching associated with minor skin irritations, inflammation, and rashes due to eczema, insect bites, poison ivy, poison oak, poison sumac, soaps, detergents, cosmetics, jewelry, seborrheic dermatitis, psoriasis and for external genital, feminine, and anal itching

Warnings

For external use only

If pregnant or breast-feeding, ask a health professional before use

Do not use

- In the eyes
- For diaper rash
- For external genital or feminine itching if you have a vaginal discharge
- More than the recommended daily dosage unless directed by a doctor
- This product in 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. Do not begin use of any other hydrocortisone product unless you have asked a doctor
- In case of bleeding when used for anal itching

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

Directions

- 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: consult a doctor
- When used for anal itching, cleanse the affected area with mild soap and warm water and rinse thoroughly. Gently dry, patting or blotting with bathroom tissue or soft cloth before applying. Children under 12: consult a doctor before using for anal itching

Other Information

- Store at room temperature
- Avoid excessive heat

Inactive Ingredients

Cetostearyl Alcohol, Glyceryl Monostearate SE, Methylchloroisothiazolinone, Propylene Glycol, Purified Water, Stearic Acid, Triethanolamine, White Soft Paraffin

Principal Display Panel - 1 oz. Tube Label

Safetec®

1% Hydrocortisone Cream

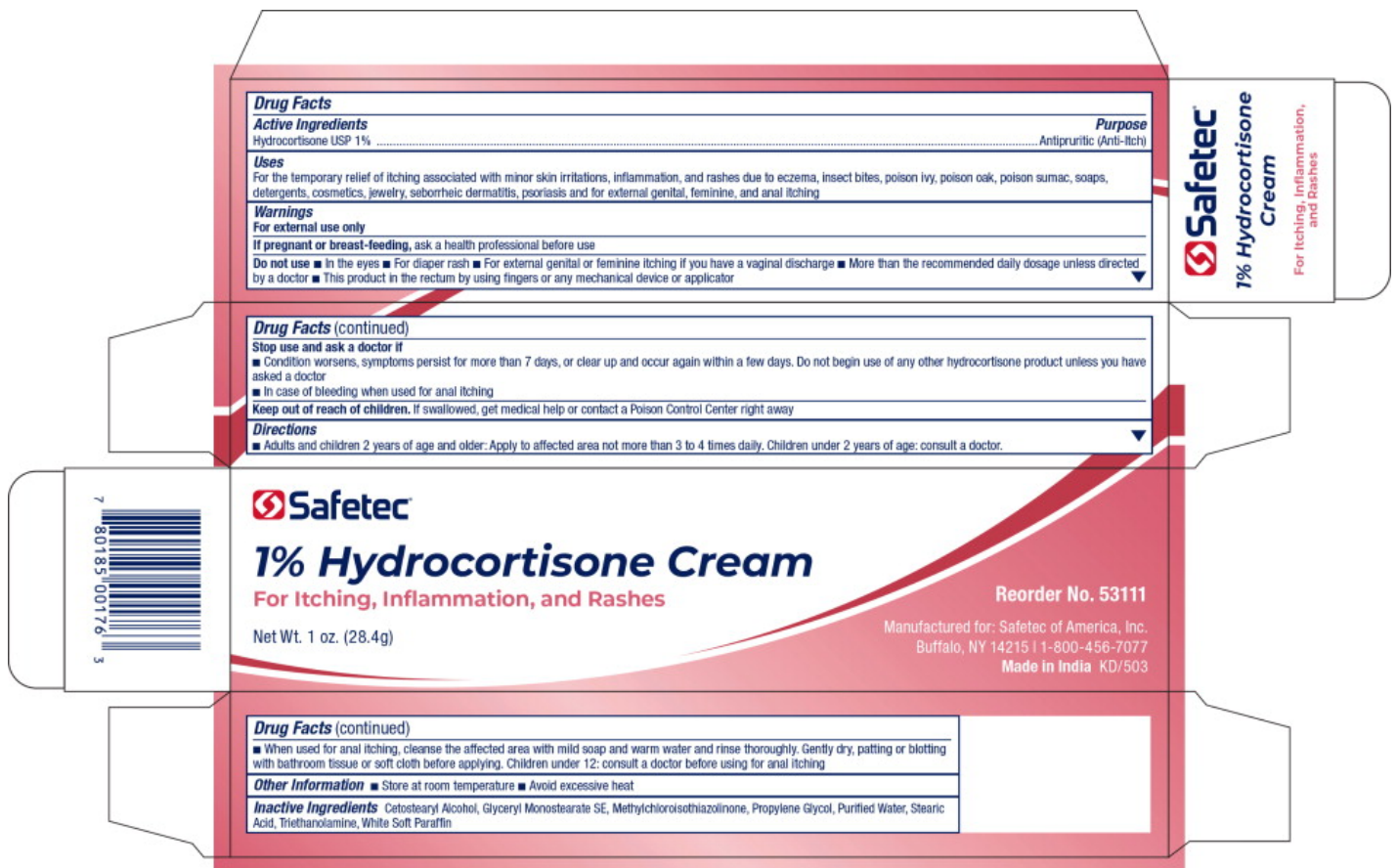
For Itching, Inflammation, and Rashes

Net Wt. 1oz. (28.4g)

Reorder No. 53111

Manufactured for: Safetec of America, Inc.
Buffalo, NY 14215 | 1-800-456-7077

Made In India KD/503



HYDROCORTISONE

hydrocortisone cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:61010-4402
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
hydrocortisone (UNII: WI4X0X7BPJ) (hydrocortisone - UNII:WI4X0X7BPJ)	hydrocortisone	10 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
GLYCERYL STEARATE SE (UNII: FCZ5MH785I)	
METHYLCHLOROISOTHIAZOLINONE (UNII: DEL7T5QRPN)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TROLAMINE (UNII: 9O3K93S3TK)	
PETROLATUM (UNII: 4T6H12BN9U)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61010-4402-1	28.4 g in 1 TUBE; Type 0: Not a Combination Product	11/01/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	11/01/2019	

Labeler - Safetec of America, Inc. (874965262)

Registrant - Safetec of America, Inc. (874965262)

Revised: 11/2019

Safetec of America, Inc.