PREPARATION H SOOTHING RELIEF ANTI-ITCH- hydrocortisone cream
GlaxoSmithKline Consumer Healthcare Holdings (US) LLC

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 ingredient

Hydrocortisone 1%

Purpose

Anti-itch

Uses

- temporary relief of external anal itching
- temporary relief of itching associated with minor skin irritations and rashes
- other uses of this product should be only under the advice and supervision of a doctor

Warnings

For external use only

Do not use 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 into the rectum by using fingers or any mechanical device or applicator

Stop use and ask a doctor if

- bleeding occurs
- 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 consulted a doctor.

Keep out of reach of children.

If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- adults: when practical, cleanse the affected area by patting or blotting with an appropriate cleansing wipe. Gently dry by patting or blotting with a tissue or soft cloth before application of this product.
- when first opening the tube, puncture foil seal with top end of cap

- adults and children 12 years of age and older: apply to the affected area not more than 3 to 4 times daily
- children under 12 years of age: do not use, consult a doctor

Other information

store at 20–25°C (68–77°F)

Inactive ingredients

anhydrous citric acid, butylated hydroxyanisole, carboxymethylcellulose sodium, cetyl alcohol, citric acid monohydrate, edetate disodium, glycerin, glyceryl oleate, glyceryl stearate, lanolin, methylparaben, propyl gallate, propylene glycol, propylparaben, purified water, simethicone emulsion, sodium benzoate, sodium lauryl sulfate, stearyl alcohol, white petrolatum, xanthan gum

Questions or comments?

Call weekdays from 9 AM to 5 PM EST at **1-800-99PrepH** or **1-800-997-7374**

PRINCIPAL DISPLAY PANEL - 26 g Tube Label

PREPARATION H®

soothing
RELIEF
anti-itch cream

HYDROCORTISONE 1%

Maximum Strength
Without a Prescription

Effective Itch Relief

No Added Fragrance

NET WT 0.9 OZ (26 g)

PRINCIPAL DISPLAY PANEL - 26 g Tube Carton

NEW!

PREPARATION H®

soothing
RELIEF
anti-itch cream

HYDROCORTISONE 1%

Maximum Strength
Without a Prescription

Effective Itch Relief

No Added Fragrance

ONE TUBE / NET WT 0.9 0Z (26 g)


NEW!
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soothing
RELIEF
anti-itch cream
HYDROCORTISONE 1%
Maximum Strength
Without a Prescription
Effective Itch Relief
No Added Fragrance
ONE TUBE / NET WT 0.9 OZ (26 g)
81% For Position Only
3 0573 0552 11 0
Drug Facts (continued)
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Drug Facts (continued)
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Drug Facts (continued)
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PREPARATION H SOOTHING RELIEF ANTI-ITCH

hydrocortisone cream

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:0573-0552
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
HYDROCORTISONE (UNII: W4X0X7BPJ) (HYDROCORTISONE - UNII:W4X0X7BPJ)	HYDROCORTISONE	10 mg in 1 g

Inactive Ingredients	
Ingredient Name	**Strength**
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
BUTYLATED HYDROXYANISOLE (UNII: REK4960K2U)	
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED FORM (UNII: K679OBS311)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	

GLYCERIN (UNII: PDC6A3C0OX)	
GLYCERYL OLEATE (UNII: 4PC054V79P)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
LANOLIN (UNII: 7EV65EAW6H)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYL GALLATE (UNII: 8D4SNN7V92)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
WATER (UNII: 059QF0KO0R)	
DIMETHICONE 350 (UNII: 2Y53S6ATLU)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
STEARYL ALCOHOL (UNII: 2KR89I4H1Y)	
PETROLATUM (UNII: 4T6H12BN9U)	
XANTHAN GUM (UNII: TTV12P4NEE)	

Product Characteristics

Color	WHITE (off-white viscous cream)	**Score**	
Shape		**Size**	
Flavor		**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0573-0552-11	1 in 1 CARTON	02/28/2020	
1		26 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part348	02/28/2020	

Labeler - GlaxoSmithKline Consumer Healthcare Holdings (US) LLC (079944263)

Revised: 7/2022 GlaxoSmithKline Consumer Healthcare Holdings (US) LLC