

PREPARATION H SOOTHING RELIEF ANTI-ITCH- hydrocortisone cream
Haleon US Holdings LLC

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 **1-800-99Prep** 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[®]

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81% For Position Only

<p>Drug Facts (continued)</p> <p>Other information store at 20-25°C (68-77°F)</p> <p>■ children under 12 years of age: do not use, consult a doctor</p> <p>■ adults and children 12 years of age and older: apply to the affected area not more than 3 to 4 times daily</p> <p>Inactive ingredients anhydrous dinitic acid, butylated hydroxytoluene, carbonylmethylcysteine sodium salt, cetyl alcohol, ethyl acetate, glycerin, glyceryl oleate, glyceryl stearate, lanolin, methylparaben, propyl gallate.</p> <p>Questions or comments? Call weekdays from 9 AM to 5 PM EST at 1-800-997-4444 or 1-800-997-7374</p>	<p>Drug Facts (continued)</p> <p>Other information store at 20-25°C (68-77°F)</p> <p>■ children under 12 years of age: do not use, consult a doctor</p> <p>■ adults and children 12 years of age and older: apply to the affected area not more than 3 to 4 times daily</p> <p>Inactive ingredients anhydrous dinitic acid, butylated hydroxytoluene, carbonylmethylcysteine sodium salt, cetyl alcohol, ethyl acetate, glycerin, glyceryl oleate, glyceryl stearate, lanolin, methylparaben, propyl gallate.</p> <p>Questions or comments? Call weekdays from 9 AM to 5 PM EST at 1-800-997-4444 or 1-800-997-7374</p>	<p>Drug Facts (continued)</p> <p>Other information store at 20-25°C (68-77°F)</p> <p>■ children under 12 years of age: do not use, consult a doctor</p> <p>■ adults and children 12 years of age and older: apply to the affected area not more than 3 to 4 times daily</p> <p>Inactive ingredients anhydrous dinitic acid, butylated hydroxytoluene, carbonylmethylcysteine sodium salt, cetyl alcohol, ethyl acetate, glycerin, glyceryl oleate, glyceryl stearate, lanolin, methylparaben, propyl gallate.</p> <p>Questions or comments? Call weekdays from 9 AM to 5 PM EST at 1-800-997-4444 or 1-800-997-7374</p>
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128 CODE ARE



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 (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	12/31/2026
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 Drug		M015	02/28/2020	12/31/2026

Labeler - Haleon US Holdings LLC (079944263)