

**PREPARATION H HYDROCORTISONE- hydrocortisone cream**  
**Haleon US Holdings LLC**

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***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 9 AM to 5 PM EST at **1-800-99PrepHor 1-800-997-7374.**

### **PRINCIPAL DISPLAY PANEL**

**NDC 0573-2830-11**

**New Look,  
SAME SIZE!**

**PREPARATION H<sup>®</sup>**

**HYDROCORTISONE 1%  
ANTI-ITCH  
CREAM**

**Relieves  
the Itch**

- **Maximum Strength** Without a Prescription
- Effective Relief of Anal Itch
- Doctor-Prescribed Ingredient

**1 TUBE | NET WT 0.9 OZ (26 g)**

# PREPARATION H<sup>®</sup>

## HYDROCORTISONE 1% ANTI-ITCH CREAM

Relieves  
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- Maximum Strength Without a Prescription
- Effective Relief of Anal Itch
- Doctor-Prescribed Ingredient

 1 TUBE | NET WT 0.9 OZ (26 g)

Do Not Use if tube seal under cap embossed with "H" is broken or missing.

For most recent product information, visit [www.preparationh.com](http://www.preparationh.com)  
Marketed by: Pfizer, Madison, NJ 07940 USA © 2018 Pfizer Inc.

### Drug Facts (continued)

- **Directions:** 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 fastening the tube, puncture the seal with top end of cap.

**New Look,  
SAME SIZE!**

### Drug Facts

**Active ingredient** ..... Purpose  
Hydrocortisone 1% ..... 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

### Drug Facts (continued)

#### 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

### Drug Facts (continued)

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.

128 CODE AREA

**New Look,  
SAME SIZE!**

- **Maximum Strength** Without a Prescription
- **Effective Relief** of Anal Itch
- **Doctor-Prescribed Ingredient**

**1 TUBE | NET WT 0.9 OZ (26 g)**

# PREPARATION<sup>H</sup>

HYDROCORTISONE 1%  
**ANTI-ITCH CREAM**

**Relieves the Itch**

**Drug Facts (continued)**

■ 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)

**Drug Facts (continued)**

**Inactive ingredients** arbutin, citric acid, butylated hydroxytoluene, carboxymethylcellulose sodium, cetyl alcohol, citric acid monohydrate, edetate disodium, glycerin, glyceryl oleate, glyceryl stearate, butolin, methylparaben, propyl galate.

**Drug Facts (continued)**

propylene glycol, propylparaben, purified water, simethicone emulsion, sodium benzoate, sodium lauryl sulfate, stearyl alcohol, white petrolatum, xanthan gum.

**Questions or comments?** Call weekdays 9 AM to 5 PM EST at 1-800-997-9974 or 1-800-997-7374

81% For Position Only

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PAA113762



## PREPARATION H HYDROCORTISONE

hydrocortisone cream

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:0573-2830
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>HYDROCORTISONE</b> (UNII: W4X0X7BPJ) (HYDROCORTISONE - UNII:W4X0X7BPJ)	HYDROCORTISONE	10 mg in 1 g

### Inactive Ingredients

Ingredient Name	Strength
<b>ANHYDROUS CITRIC ACID</b> (UNII: XF417D3PSL)	
<b>BUTYLATED HYDROXYANISOLE</b> (UNII: REK4960K2U)	
<b>CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED</b> (UNII: K679OBS311)	
<b>CETYL ALCOHOL</b> (UNII: 936JST6JCN)	
<b>CITRIC ACID MONOHYDRATE</b> (UNII: 2968PHW8QP)	
<b>EDETATE DISODIUM</b> (UNII: 7FLD91C86K)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>GLYCERYL OLEATE</b> (UNII: 4PC054V79P)	
<b>GLYCERYL MONOSTEARATE</b> (UNII: 230OU9XXE4)	
<b>LANOLIN</b> (UNII: 7EV65EAW6H)	
<b>METHYLPARABEN</b> (UNII: A2I8C7HI9T)	
<b>PROPYL GALLATE</b> (UNII: 8D4SNN7V92)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>PROPYLPARABEN</b> (UNII: Z8IX2SC1OH)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>DIMETHICONE 350</b> (UNII: 2Y53S6ATLU)	
<b>SODIUM BENZOATE</b> (UNII: OJ245FE5EU)	
<b>SODIUM LAURYL SULFATE</b> (UNII: 368GB5141J)	
<b>STEARYL ALCOHOL</b> (UNII: 2KR89I4H1Y)	
<b>PETROLATUM</b> (UNII: 4T6H12BN9U)	
<b>XANTHAN GUM</b> (UNII: TTV12P4NEE)	

### Product Characteristics

<b>Color</b>	white (off-white viscous cream)	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>		<b>Imprint Code</b>	

**Contains****Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0573-2830-10	1 in 1 CARTON	01/01/2004	
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	01/01/2004	

**Labeler** - Haleon US Holdings LLC (079944263)

Revised: 2/2024

Haleon US Holdings LLC