

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 **1-800-99PrepHor 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)

Questions or comments? Call weekdays 9 AM to 5 PM EST at
1-800-99PrepH or 1-800-997-7374

For most recent product information, visit www.preparationh.com
Marketed by: Pfizer, Madison, NJ 07940 USA © 2019 Pfizer Inc.

THIS PACKAGE CONTAINS AN OUTER CARTON. DO NOT BUY IF OUTER CARTON IS MISSING.

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

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Active ingredient Hydrocortisone 1%

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

PAA134608

PRINCIPAL DISPLAY PANEL - 26 g Tube Carton

NEW!

PREPARATION H[®]

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RELIEF
anti-itch cream

HYDROCORTISONE 1%

Maximum Strength
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ONE TUBE / NET WT 0.9 OZ (26 g)

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81% For Position Only
3 0573 0552 11 0

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: anhydrous propylene glycol, propylparaben, purified water, simethicone emulsion, sodium benzoate, sodium lauryl sulfate, stearylalcohol, white petrolatum, xanthan gum	Drug Facts (continued) Questions or comments? Call weekdays from 9 AM to 5 PM EST at 1-800-997-4PH1 or 1-800-997-7324
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PREPARATION H®

soothing RELIEF anti-itch cream

HYDROCORTISONE 1%

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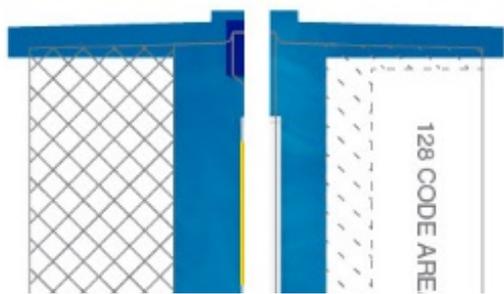
No Added
Fragrance

ONE TUBE
NET WT 0.9 OZ (26g)

PREPARATION H®

soothing RELIEF

Drug Facts Active ingredient Purpose Hydrocortisone 1%Anti-itch	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.
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		





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	
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	

Labeler - Haleon US Holdings LLC (079944263)