

PREPARATION H RAPID RELIEF- glycerin, lidocaine, petrolatum, and phenylephrine hydrochloride cream

Wyeth Consumer Healthcare 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.

Preparation H[®] Rapid Relief

Drug Facts

<i>Active ingredients</i>	<i>Purposes</i>
Glycerin 14.4%	Protectant
Lidocaine 5%	Local anesthetic
Phenylephrine HCl 0.25%	Vasoconstrictor
White petrolatum 15%	Protectant

Uses

- for temporary relief of pain, soreness and burning
- helps relieve the local itching and discomfort associated with hemorrhoids
- temporarily shrinks hemorrhoidal tissue
- temporarily provides a coating for relief of anorectal discomforts
- temporarily protects the inflamed irritated anorectal surface to help make bowel movements less painful

Warnings

For external use only

Ask a doctor before use if you have

- heart disease
- high blood pressure
- thyroid disease
- diabetes
- difficulty in urination due to enlargement of the prostate gland

Ask a doctor or pharmacist before use if you are presently taking a prescription drug for high blood pressure or depression.

When using this product

- 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 or does not improve within 7 days
- an allergic reaction develops
- the symptom being treated does not subside or if redness, irritation, swelling, pain, or other symptoms develop or increase

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

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 a soft cloth before applying this cream.
- apply externally to the affected area up to 4 times daily, especially at night, in the morning or after each bowel movement
- children under 12 years of age: ask a doctor

Other information

store at 20-25°C (68-77°F)

Inactive ingredients

aloe barbadensis leaf extract, anhydrous citric acid, butylated hydroxyanisole, carboxymethylcellulose sodium, cetyl alcohol, citric acid monohydrate, dexpanthenol, edetate disodium, glyceryl monostearate, methylparaben, mineral oil, polyoxyl lauryl ether, polyoxyl stearyl ether, propyl gallate, propylene glycol, propylparaben, purified water, sodium benzoate, stearyl alcohol, tocopherols excipient, vitamin E acetate, xanthan gum

Questions or comments?

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

PRINCIPAL DISPLAY PANEL - 23 g Tube Label

To open: push down on cap while turning counterclockwise.

Child-Resistant Cap

PREPARATION H[®]

HEMORRHOIDAL CREAM

RAPID RELIEF

WITH LIDOCAINE

- Rapid numbing relief of pain, itching & burning
- Reduces swelling & provides a soothing protective layer

NET WT 0.75 OZ (23g)

Mkt'd by: Pfizer, Madison, NJ 07940 USA © 2018 Pfizer Inc.

For most recent product information, visit www.preparationh.com

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

To open: push down on cap while turning counterclockwise.

Child-Resistant Cap

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Active ingredients (in each tube) Glycerin 14.4%, Lidocaine 5%, Phenylephrine HCl 0.25%, White petrolatum 15%,

Uses for the temporary relief of pain, soreness, and burning; helps relieve the local itching and discomfort associated with hemorrhoids; temporarily shrinks hemorrhoidal tissue; temporarily provides a coating for relief of anorectal discomforts; temporarily protects the inflamed, irritated anorectal surface to help make bowel movements less painful.

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Made in Canada

PAA105969



PRINCIPAL DISPLAY PANEL - 23 g Tube Carton

PREPARATION H[®]

New Benefit
Now Reduces Swelling
See new label

RAPID RELIEF
WITH
LIDOCAINE

HEMORRHOIDAL
CREAM

LIDOCAINE
PHENYLEPHRINE HCl
GLYCERIN
WHITE PETROLATUM

5%
HIGHEST STRENGTH
LIDOCAINE

AVAILABLE

- Rapid numbing relief of pain, itching & burning
- Reduces swelling & provides a soothing protective layer

1 TUBE | NET WT 0.75 OZ (23 g)



Do Not Use if seals imprints with "Preparation H" on outer carton are broken or missing.

New Benefit
Now Reduces Swelling
See new label

PREPARATION H

RAPID RELIEF
WITH
LIDOCAINE

HEMORRHOIDAL CREAM

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PREPARATION H

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Drug Facts (continued)

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Questions or comments?
Call weekdays 9AM to 5 PM EST at 1-800-900PrepH or 1-800-997-7374

81% For Position Only

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Made by: Pfizer, Madison, NJ 07740 USA
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For most recent product information, visit www.preparationh.com

PAA100635

PREPARATION H RAPID RELIEF

glycerin, lidocaine, petrolatum, and phenylephrine hydrochloride cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0573-2843
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
GLYCERIN (UNII: PDC6A3C0OX) (GLYCERIN - UNII:PDC6A3C0OX)	GLYCERIN	144 mg in 1 g
LIDOCAINE (UNII: 98PI200987) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE	50 mg in 1 g
PETROLATUM (UNII: 4T6H12BN9U) (PETROLATUM - UNII:4T6H12BN9U)	PETROLATUM	150 mg in 1 g
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	2.5 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
BUTYLATED HYDROXYANISOLE (UNII: REK4960K2U)	
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED FORM (UNII: K679OBS311)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
DEXPANTHENOL (UNII: 1O6C93RI7Z)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
METHYL PARABEN (UNII: A2I8C7HI9T)	
MINERAL OIL (UNII: T5L8T28FGP)	
LAURETH-23 (UNII: N72LMW566G)	
STEARETH-2 (UNII: V56DFE46J5)	
STEARETH-20 (UNII: L0Q8IK9E08)	
PROPYL GALLATE (UNII: 8D4SNN7V92)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PROPYL PARABEN (UNII: Z8IX2SC1OH)	
WATER (UNII: 059QF0KO0R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
STEARYL ALCOHOL (UNII: 2KR89I4HIY)	
TOCOPHEROL (UNII: R0ZB2556P8)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
XANTHAN GUM (UNII: TTV12P4NEE)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0573-2843-01	1 in 1 CARTON	11/01/2018	
1		23 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:0573-2843-10	1 in 1 CARTON	11/01/2018	
2		28 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 FINAL	part346	11/01/2018	

Labeler - Wyeth Consumer Healthcare LLC (828831730)

Establishment

Name	Address	ID/FEI	Business Operations
PF Consumer Healthcare Canada ULC		203812479	ANALYSIS(0573-2843) , LABEL(0573-2843) , MANUFACTURE(0573-2843) , PACK(0573-2843)

Revised: 1/2019

Wyeth Consumer Healthcare LLC