

PREPARATION H MAXIMUM STRENGTH- glycerin, petrolatum, phenylephrine hcl, pramoxine hcl cream
Haleon US Holdings LLC

PREPARATION H®

Drug Facts

Active ingredients Purposes

Glycerin 14.4%	Protectant
Phenylephrine HCl 0.25%	Vasoconstrictor
Pramoxine HCl 1%	Local anesthetic
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 cream.
- when first opening the tube, puncture foil seal with top end of cap
- apply externally or in the lower portion of the anal canal only
- apply externally to the affected area up to 4 times daily, especially at night, in the morning or after each bowel movement
- for application in the lower anal canal: remove cover from dispensing cap. Attach dispensing cap to tube. Lubricate dispensing cap well, then gently insert dispensing cap partway into the anus.
- thoroughly cleanse dispensing cap after each use and replace cover
- 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 - 26 g Tube Carton

PREPARATION H[®]

HEMORRHOIDAL
CREAM

Multi-Symptom
Pain Relief

WITH
ALOE

New Look,
SAME SIZE!

- Soothing Pain Relief from Burning, Itching, & Discomfort
- Shrinks Swollen Hemorrhoidal Tissue

- Protects Irritated Tissue
- Relieves External Discomfort
- Proprietary Blend with Vitamin E and Aloe

1 TUBE | NET WT 0.9 OZ (26 g)



PRINCIPAL DISPLAY PANEL - 51 g Tube Carton

PREPARATION H® HEMORRHOIDAL CREAM

Maximum Strength Pain Relief

Smooth Cream Formula with Aloe

1. Rapid, Soothing Pain Relief from Painful

Burning, Itching and Discomfort

2. Shrinks Swollen Hemorrhoidal Tissue
3. Protects Irritated Tissue
4. Relieves External Discomfort

NET WT. 1.8 OZ (51 g)

Drug Facts (continued)

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.

Drug Facts (continued)

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 cream.
- when first opening the tube, puncture foil seal with top end of cap
- apply externally or in the lower portion of the anal canal only
- apply externally to the affected area up to 4 times daily, especially at night, in the morning or after each bowel movement
- for application in the lower anal canal: remove cover from dispensing cap. Attach dispensing cap to tube. Lubricate dispensing cap well, then gently insert dispensing cap partway into the anus.



Drug Facts (continued)

- thoroughly cleanse dispensing cap after each use and replace cover
- 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

Drug Facts (continued)

Questions or comments? Call weekdays 9 AM to 5 PM EST at 1-800-99PrepH or 1-800-987-7374.

PREPARATION H[®]
HEMORRHOIDAL CREAM

Maximum Strength Pain Relief

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Maximum Strength Pain Relief

Smooth Cream Formula with Aloe

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NET WT. 1.8 OZ (51 g)

Drug Facts

Active ingredients

Glycerin 14.4%	Protectant
Phenylephrine HCl 0.25%	Vasoconstrictor
Pramoxine HCl 1%	Local anesthetic
White petrolatum 15%	Protectant

Purposes

Uses

- for temporary relief of pain, soreness and burning
- helps relieve the local itching and discomfort associated with hemorrhoids

Drug Facts (continued)

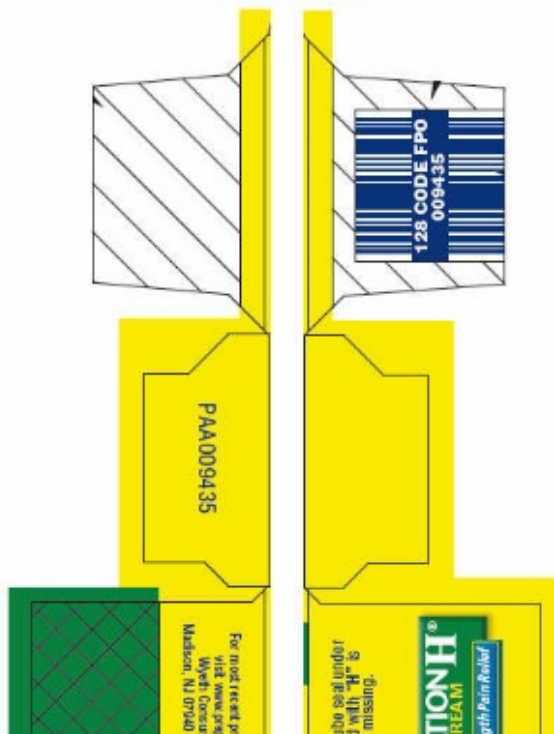
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- temporarily provides a coating for relief of anorectal discomforts
- temporarily protects the inflamed, irritated anorectal surface to help make bowel movements less painful

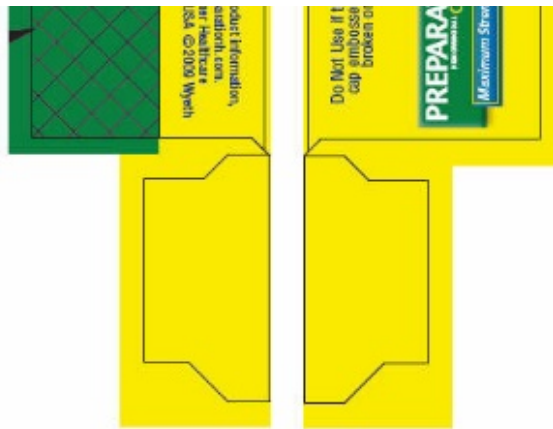
Warnings

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





PRINCIPAL DISPLAY PANEL - 51 g Tube Carton - NDC 0573-2868-98

PREPARATION H[®]

HEMORRHOIDAL
CREAM

Multi-Symptom
Pain Relief

WITH
ALOE

- Soothing Pain Relief from Burning, Itching, & Discomfort
- Shrinks Swollen Hemorrhoidal Tissue
- Protects Irritated Tissue
- Relieves External Discomfort
- Proprietary Blend with Vitamin E and Aloe

1 TUBE | NET WT 1.8 OZ (51 g)

PREPARATION H[®]

HEMORRHOIDAL CREAM

Multi-Symptom Pain Relief

- Soothing Pain Relief from Burning, Itching, & Discomfort
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1 TUBE | NET WT 1.8 OZ (51 g)

Drug Facts (continued)

Directions
 ■ After each use, gently clean the affected area by patting dry with a soft cloth. Do not use Preparation H Cream on the rectum or inside the rectum.
 ■ When first opening the tube, underwear should be worn with top and bottom flaps open.
 ■ Apply a thin layer of cream to the affected area 3 to 4 times daily, especially at night, in the morning or after each bowel movement.

Drug Facts (continued)

■ For application to the lower anal canal, carefully insert the nozzle of the tube into the rectum and gently depress the cap. Each depression will deliver a small amount of cream.
 ■ The tube is designed to be used only once.
 ■ Do not use Preparation H Cream if the cap is broken or missing.

Drug Facts (continued)

Other information
 ■ Store at 20-25°C (68-77°F).
 ■ Keep out of reach of children under 12 years of age. Ask a doctor before use if you are pregnant, nursing, or taking other medicine.
 ■ Contains 1.8 oz (51 g) of cream.

Drug Facts (continued)

Questions or comments? Call us at 1-800-997-7374. We'll be glad to help you. For more information, visit www.preph.com.
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 For US Patient App, look for details at www.preph.com.

81% For Position Only
 5 0573 2868 98 1

PREPARATION H[®]

HEMORRHOIDAL CREAM

Multi-Symptom Pain Relief



- Soothing Pain Relief from Burning, Itching, & Discomfort
- Shrinks Swollen Hemorrhoidal Tissue
- Protects Irritated Tissue
- Relieves External Discomfort
- Proprietary Blend with Vitamin E and Aloe

1 TUBE | NET WT 1.8 OZ (51 g)

Drug Facts (continued)
 ■ 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.

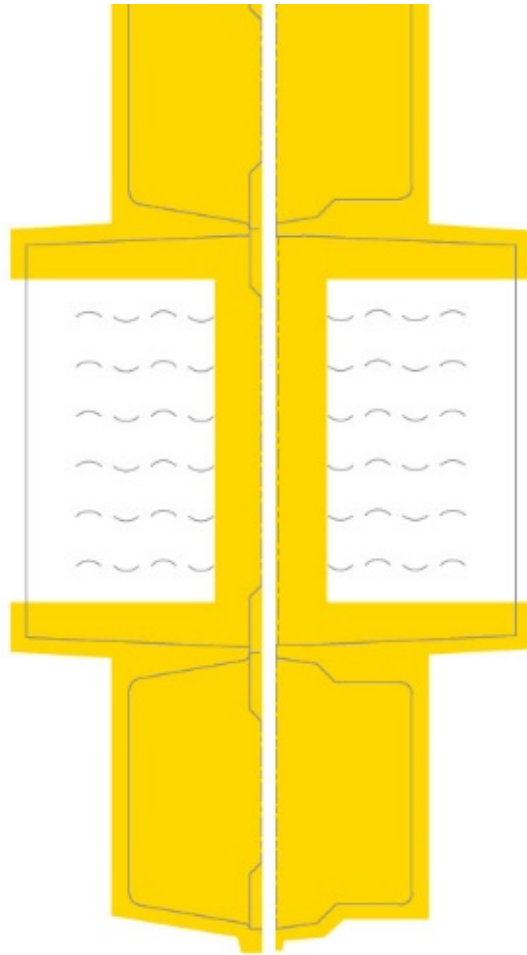
Drug Facts (continued)
 ■ temporarily shrinks hemorrhoidal tissue
 ■ temporarily provides a coating for relief of anorectal discomforts
 ■ temporarily protects the inflamed, irritated anorectal surface to help make bowel movements less painful
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 Ask a doctor before use if you have:
 ■ heart disease ■ high blood pressure
 ■ thyroid disease ■ diabetes

Drug Facts
Active ingredients
 Glycerin 14.4%.....Protectant
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Purposes
 ■ for temporary relief of pain, soreness and burning
 ■ helps relieve the local itching and discomfort associated with hemorrhoids

PREPARATION H[®]
HEMORRHOIDAL CREAM

PA1136152

Drug Facts (continued)
Stop use and ask a doctor if:
 ■ bleeding occurs
 ■ condition worsens or does not improve within 7 days
 ■ an allergic reaction develops
 ■ the symptoms have not improved 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.



PREPARATION H MAXIMUM STRENGTH

glycerin, petrolatum, phenylephrine hcl, pramoxine hcl cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0573-2868
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
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	2.5 mg in 1 g
PRAMOXINE HYDROCHLORIDE (UNII: 88AYB867L5) (PRAMOXINE - UNII:068X84E056)	PRAMOXINE HYDROCHLORIDE	10 mg in 1 g
PETROLATUM (UNII: 4T6H12BN9U) (PETROLATUM - UNII:4T6H12BN9U)	PETROLATUM	150 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
BUTYLATED HYDROXYANISOLE (UNII: REK4960K2U)	
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED (UNII: K679OBS311)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
DEXPANTHENOL (UNII: 1O6C93RI7Z)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
LAURETH-23 (UNII: N72LMW566G)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
MINERAL OIL (UNII: T5L8T28FGP)	
PROPYL GALLATE (UNII: 8D4SNN7V92)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
STEARYL ALCOHOL (UNII: 2KR89I4H1Y)	
WATER (UNII: 059QF0KO0R)	
XANTHAN GUM (UNII: TTV12P4NEE)	

Product Characteristics

Color	white	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0573-2868-10	1 in 1 CARTON	07/01/2004	
1		26 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:0573-2868-20	1 in 1 CARTON	07/01/2004	
2		51 g in 1 TUBE; Type 0: Not a Combination Product		
3	NDC:0573-2868-93	1 in 1 CARTON	01/01/2019	
3		26 g in 1 TUBE; Type 0: Not a Combination Product		
4	NDC:0573-2868-98	1 in 1 CARTON	05/12/2020	
4		51 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	07/01/2004	

Labeler - Haleon US Holdings LLC (079944263)

Revised: 4/2024

Haleon US Holdings LLC