

**PREPARATION H- mineral oil, petrolatum, phenylephrine hcl ointment**  
**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.*

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**Preparation H Hemorrhoidal Ointment**  
**(mineral oil, petrolatum and phenylephrine HCl)**

**DRUG FACTS**

**ACTIVE INGREDIENTS**

Mineral oil 14%

Petrolatum 74.9%

Phenylephrine HCl 0.25%

**PURPOSES**

Protectant

Protectant

Vasoconstrictor

**USES**

- helps relieve the local itching and discomfort associated with hemorrhoids
- temporarily shrinks hemorrhoidal tissue and relieves burning
- 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 and/or intrarectal 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.

**Stop use and ask a doctor if**

- bleeding occurs
- condition worsens or does not improve within 7 days
- introduction of applicator into the rectum causes additional pain

**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 ointment.
- when first opening the tube, puncture foil seal with top end of cap
- apply to the affected area up to 4 times daily, especially at night, in the morning or after each bowel movement
- intrarectal use:
  - remove cover from applicator, attach applicator to tube, lubricate applicator well and gently insert applicator into the rectum
  - thoroughly cleanse applicator after each use and replace cover
- also apply ointment to external area
- regular use provides continual therapy for relief of symptoms
- children under 12 years of age: ask a doctor

**OTHER INFORMATION**

store at 20-25°C (68-77°F)

**INACTIVE INGREDIENTS**

benzoic acid, butylated hydroxyanisole, corn oil, glycerin, lanolin, lanolin alcohols, methylparaben, mineral oil, paraffin, propylparaben, purified water, thymus vulgaris (thyme) flower/leaf oil, tocopherols excipient, white wax

**QUESTIONS OR COMMENTS?**

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

**PRINCIPAL DISPLAY PANEL - 28 g Tube Label**

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

PREPARATION H<sup>®</sup>  
HEMORRHOIDAL OINTMENT

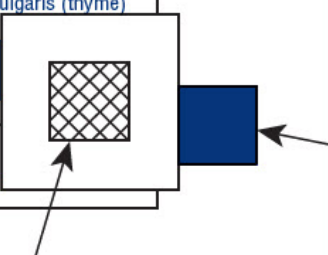
Prevents Further  
Irritation

- Prompt, Soothing Relief from Painful Burning, Itching and Discomfort
- Shrinks Swollen Hemorrhoidal Tissue
- Protects Irritated Tissue

- Relieves Internal and External Discomfort

NET WT 1 OZ (28 g)

THIS PACKAGE CONTAINS AN OUTER CARTON. DO NOT BUY IF OUTER CARTON IS MISSING.	
<h1 style="margin: 0;">PREPARATION H<sup>®</sup></h1> <h2 style="margin: 0;">HEMORRHOIDAL OINTMENT</h2>	<p><b>Prevents Further Irritation</b></p> <ul style="list-style-type: none"> <li>Prompt, Soothing Relief from Painful Burning, Itching and Discomfort</li> <li>Shrinks Swollen Hemorrhoidal Tissue</li> <li>Protects Irritated Tissue</li> <li>Relieves Internal and External Discomfort</li> </ul> <p><b>NET WT 1 OZ (28 g)</b></p>
<p><b>Active ingredients</b> Mineral oil 14%, Petrolatum 74.9%, Phenylephrine HCl 0.25%</p> <p><b>Uses</b> helps relieve the local itching and discomfort associated with hemorrhoids; temporarily shrinks hemorrhoidal tissue and relieves burning; temporarily provides a coating for relief of anorectal discomforts; temporarily protects the inflamed, irritated anorectal surface to help make bowel movements less painful.</p> <p><b>Warnings</b>  <b>For external and/or intrarectal use only</b>  <b>Ask a doctor before use if you have</b> heart disease; high blood pressure; thyroid disease; diabetes; difficulty in urination due to enlargement of the prostate gland.  <b>Ask a doctor or pharmacist before use if you are</b> presently taking a prescription drug for high blood pressure or depression.  <b>When using this product</b> do not exceed the recommended daily dosage unless directed by a doctor.  <b>Stop use and ask a doctor if</b> bleeding occurs; condition worsens or does not improve within 7 days; introduction of applicator into the rectum causes additional pain.  <b>If pregnant or breast-feeding,</b> ask a health professional before use.  <b>Keep out of reach of children.</b> If swallowed, get medical help or contact a Poison Control Center right away.</p>	<p><b>Directions</b> 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 ointment; when first opening the tube, puncture foil seal with top end of cap; apply to the affected area up to 4 times daily, especially at night, in the morning or after each bowel movement. <b>Intrarectal use:</b> remove cover from applicator, attach applicator to tube, lubricate applicator well and gently insert applicator into the rectum, thoroughly cleanse applicator after each use and replace cover; also apply ointment to external area; regular use provides continual therapy for relief of symptoms. Children under 12 years of age: ask a doctor.</p> <p><b>Other information</b> store at 20-25°C (68-77°F)</p> <p><b>Inactive ingredients</b> benzoic acid, butylated hydroxyanisole, corn oil, glycerin, lanolin, lanolin alcohols, methylparaben, mineral oil, paraffin, propylparaben, purified water, thymus vulgaris (thyme) flower/leaf oil, tocopherols excipient, white wax</p> <div style="border: 1px solid black; padding: 2px; width: fit-content; margin: 5px auto;"> <p style="font-size: x-small; margin: 0;">Do Not Use if tube seal under cap embossed with "H" is broken or missing.</p> </div> <p>For most recent product information, visit <a href="http://www.preparationh.com">www.preparationh.com</a>  Marketed by: Pfizer, Madison, NJ 07940 USA  © 2016 Pfizer Inc. <span style="float: right;">PAA071386</span></p>



### PRINCIPAL DISPLAY PANEL - 28 g Tube Carton

## PREPARATION H<sup>®</sup> HEMORRHOIDAL OINTMENT

### Prevents Further Irritation

- Prompt, Soothing Relief from Painful Burning, Itching and Discomfort
- Shrinks Swollen Hemorrhoidal Tissue
- Protects Irritated Tissue
- Relieves Internal and External Discomfort

NET WT 1 OZ (28 g)



**PRINCIPAL DISPLAY PANEL - 28 g Tube Label - PAA119867**

PREPARATION H®  
HEMORRHOIDAL  
OINTMENT

Prevents Further  
Irritation

- Prompt, Soothing Relief from Painful Burning, Itching, & Discomfort
- Shrinks Swollen Hemorrhoidal Tissue
- Protects Irritated Tissue
- Relieves Internal & External Discomfort

NET WT 1.0 OZ (28 g)



**PRINCIPAL DISPLAY PANEL - 28 g Tube Carton - PAA119868**

PREPARATION H®

HEMORRHOIDAL  
OINTMENT

Prevents Further  
Irritation

New Look,  
SAME SIZE!

- Prompt, Soothing Relief from Painful Burning, Itching, & Discomfort
- Shrinks Swollen Hemorrhoidal Tissue
- Protects Irritated Tissue
- Relieves Internal & External Discomfort

1 TUBE | NET WT 1 OZ (28 g)

# PREPARATION H®

## HEMORRHOIDAL OINTMENT

Prevents Further Irritation

New Look, SAME SIZE!

- Prompt, Soothing Relief from Painful Burning, Itching, & Discomfort
- Shrinks Swollen Hemorrhoidal Tissue
- Protects Irritated Tissue
- Relieves Internal & External Discomfort

1 TUBE | NET WT 1 OZ (28 g)

### Drug Facts (continued)

- Intra-rectal use:
  - remove cover from applicator, attach applicator to tube, lubricate applicator well
  - and gently insert applicator into the rectum
  - thoroughly cleanse applicator after each use and replace cover
  - also apply ointment to external area
  - after use provides continued therapy for relief of symptoms
  - children under 12 years of age: ask a doctor

### Drug Facts (continued)

**Other information:** store at 20-25°C (68-77°F)

**Inactive ingredients:** boric acid, butylated hydroxyanisole, corn oil, glycerin, lanolin, lanolin alcohols, methylparaben, mineral oil, paraffin, propylparaben, purified water, thymus vulgaris (thyme) flower/leaf oil, thopherols extract, white wax

### 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](http://www.preparationh.com)  
Marketed by: Pfizer, Madison, NJ 07940 USA  
© 2019 Pfizer Inc. Made in Canada

Do Not Use if tube seal is broken or missing.

81% For Position Only

3 0573 2871 93 6

# PREPARATION H®

## HEMORRHOIDAL OINTMENT

Prevents Further Irritation

- Prompt, Soothing Relief from Painful Burning, Itching, & Discomfort
- Shrinks Swollen Hemorrhoidal Tissue
- Protects Irritated Tissue
- Relieves Internal & External Discomfort

1 TUBE | NET WT 1 OZ (28 g)

New Look, SAME SIZE!

### Drug Facts

**Active ingredients**      **Purposes**  
Mineral oil 14% ..... Protectant  
Petrolatum 74.9% ..... Protectant  
Phenylephrine HCl 0.25% ..... Vasoconstrictor

### Uses

- helps relieve the local itching and discomfort associated with hemorrhoids
- temporarily shrinks hemorrhoidal tissue and relieves burning

### Drug Facts (continued)

- 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 and/or intra-rectal use only  
Ask a doctor before use if you have  
■ heart disease    ■ high blood pressure

### Drug Facts (continued)

- thyroid disease    ■ diabetes
- difficulty in urination due to enlargement of the prostate gland

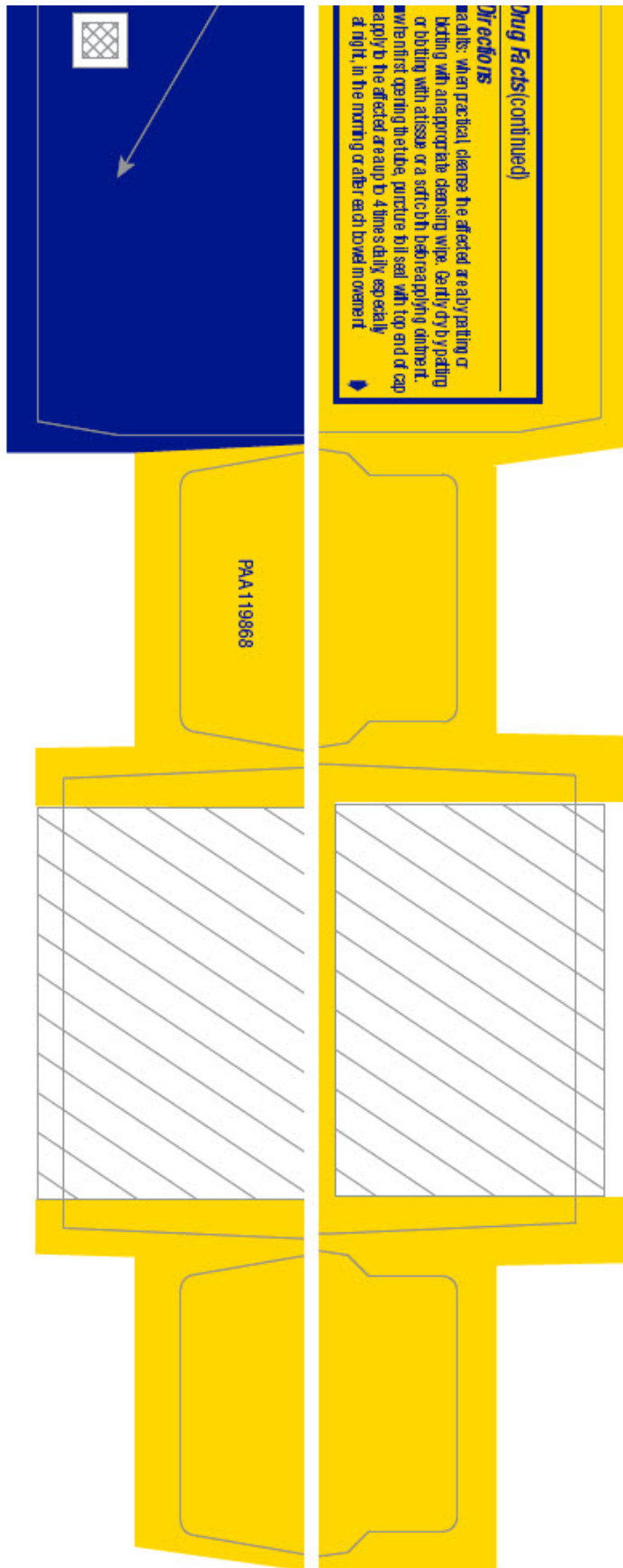
Ask a doctor or pharmacist before use if you are presently taking a prescription drug for high blood pressure or depression.

When using this product do not exceed the recommended daily dosage unless directed by a doctor

### Drug Facts (continued)

- Stop use and ask a doctor if
- bleeding occurs
  - condition worsens or does not improve within 7 days
  - introduction of applicator into the rectum causes additional pain

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.



**PRINCIPAL DISPLAY PANEL - 57 g Tube Label**  
PREPARATION H®

# HEMORRHOIDAL OINTMENT

Prevents Further  
Irritation

- Prompt, Soothing Relief from Painful Burning, Itching, & Discomfort
- Shrinks Swollen Hemorrhoidal Tissue
- Protects Irritated Tissue
- Relieves Internal & External Discomfort

NET WT 2.0 OZ (57 g)

<b>Questions or comments?</b> Call weekdays 9 AM to 5 PM EST at 1-800-99PrepH or 1-800-997-7374		<b>THIS PACKAGE CONTAINS AN OUTER CARTON. DO NOT BUY IF OUTER CARTON IS MISSING.</b>	
For most recent product information, visit <a href="http://www.preparationh.com">www.preparationh.com</a> Marketed by: Pfizer, Madison, NJ 07940 USA © 2020 Pfizer Inc.		Do Not Use if tube seal under cap embossed with "H" is broken or missing.	
<b>PREPARATION H<sup>®</sup></b>		<b>HEMORRHOIDAL OINTMENT</b>	<ul style="list-style-type: none"><li>• Prompt, Soothing Relief from Painful Burning, Itching, &amp; Discomfort</li><li>• Shrinks Swollen Hemorrhoidal Tissue</li><li>• Protects Irritated Tissue</li><li>• Relieves Internal &amp; External Discomfort</li></ul>
<b>NET WT 2.0 OZ (57 g)</b>		<b>Prevents Further Irritation</b>	
<b>Active Ingredients</b> Mineral oil 14%, Petrolatum 74.9%, Phenylephrine HCl 0.25% <b>Uses</b> helps relieve the local itching and discomfort associated with hemorrhoids; temporarily shrinks hemorrhoidal tissue and relieves burning; temporarily provides a coating for relief of anorectal discomforts; temporarily protects the inflamed, irritated anorectal surface to help make bowel movements less painful. <b>Warnings</b> <b>For external and/or intrarectal use only</b> <b>Ask a doctor before use if you have</b> heart disease; high blood pressure; thyroid disease; diabetes; difficulty in urination due to enlargement of the prostate gland. <b>Ask a doctor or pharmacist before use if you are</b> presently taking a prescription drug for high blood pressure or depression. <b>When using this product</b> do not exceed the recommended daily dosage unless directed by a doctor. <b>Stop use and ask a doctor if</b> bleeding occurs; condition worsens or does not improve within 7 days; introduction of applicator into the rectum causes additional pain.		<b>If pregnant or breast-feeding</b> , ask a health professional before use. <b>Keep out of reach of children.</b> If swallowed, get medical help or contact a Poison Control Center right away. <b>Directions</b> 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 ointment; when first opening the tube, puncture foil seal with top end of cap; apply to the affected area up to 4 times daily, especially at night, in the morning or after each bowel movement. <b>Intrarectal use:</b> remove cover from applicator, attach applicator to tube, lubricate applicator well and gently insert applicator into the rectum, thoroughly cleanse applicator after each use and replace cover; also apply ointment to external area; regular use provides continual therapy for relief of symptoms. Children under 12 years of age: ask a doctor. <b>Other Information</b> store at 20-25°C (68-77°F) <b>Inactive Ingredients</b> benzoic acid, butylated hydroxyanisole, corn oil, glycerin, lanolin, lanolin alcohols, methylparaben, mineral oil, paraffin, propylparaben, purified water, thymus vulgaris (thyme) flower/leaf oil, tocopherols excipient, white wax	
		 PAA136097	

## PRINCIPAL DISPLAY PANEL - 57 g Tube Carton

# PREPARATION H<sup>®</sup> HEMORRHOIDAL OINTMENT

Prevents Further  
Irritation

- Prompt, Soothing Relief from Painful Burning, Itching, & Discomfort
- Shrinks Swollen Hemorrhoidal Tissue
- Protects Irritated Tissue



- Relieves Internal & External Discomfort

1 TUBE | NET WT 2 OZ (57 g)

# PREPARATION H<sup>®</sup>

## HEMORRHOIDAL OINTMENT

Prevents Further Irritation

- Prompt, Soothing Relief from Painful Burning, Itching, & Discomfort
- Shrinks Swollen Hemorrhoidal Tissue
- Protects Irritated Tissue
- Relieves Internal & External Discomfort

 1 TUBE | NET WT 2 OZ (57 g)

81% For Position Only  
3 0573 2871 94 3

Do Not Use if tube seal under cap embossed with "H" is broken or missing.  
For most recent product information, visit [www.pfizer.com](http://www.pfizer.com).  
Made in Canada  
© 2020 Pfizer Inc.  
Manufactured by: Pfizer, Madison, NJ 07940 USA

**Drug Facts (continued)**

**Interactal use:**

- remove cover from applicator, attach applicator to tube.
- lubricate applicator well and gently insert applicator into the rectum.
- thoroughly cleanse applicator after each use and replace cover cap.
- also apply ointment to external area.
- regular use provides continual therapy for relief of symptoms.
- children under 12 years of age: ask a doctor.

**Other information:** store at 20-28°C (68-77°F).

**Drug Facts (continued)**

**Inactive ingredients:** benzocaine, butylated hydroxyanisole, camphor, glycerin, lanolin alcohols, methylparaben, mineral oil, petrolatum, polypropylene glycol, purified water, thymus virginiana (thyme) flower leaf oil, tocopherols, zinc oxide.

**Questions or comments?**  
Call weekdays 9 AM to 5 PM EST at 1-800-999-REPH or 1-800-999-7374

# PREPARATION H<sup>®</sup>

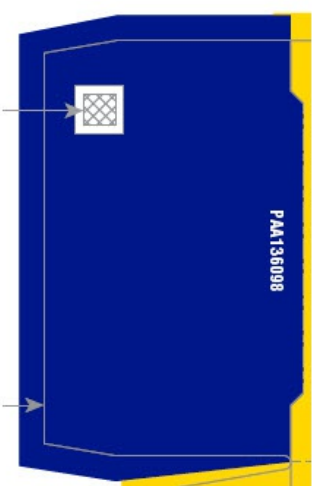
## HEMORRHOIDAL OINTMENT

Prevents Further Irritation

- Prompt, Soothing Relief from Painful Burning, Itching, & Discomfort
- Shrinks Swollen Hemorrhoidal Tissue
- Protects Irritated Tissue
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 1 TUBE | NET WT 2 OZ (57 g)

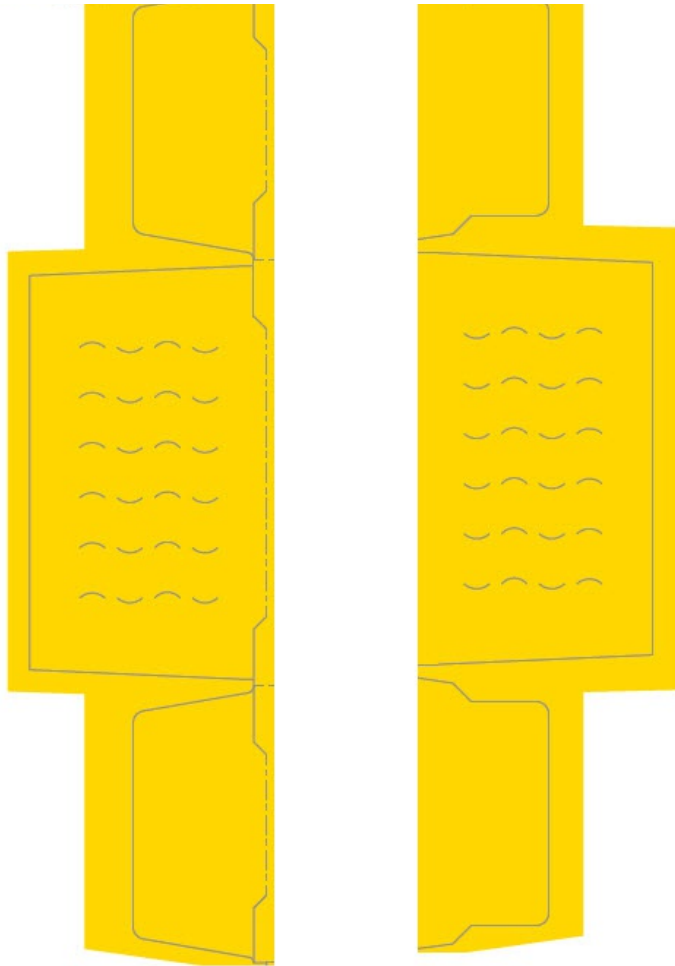
<p><b>Drug Facts</b></p> <p><b>Active ingredients</b></p> <p>Mineral oil 14% ..... Protectant Petrolatum 74.9% ..... Protectant Phenylephrine HCl 0.25% ..... Vasoconstrictor</p> <p><b>Purposes</b></p> <p>Mineral oil 14% ..... Protectant Petrolatum 74.9% ..... Protectant Phenylephrine HCl 0.25% ..... Vasoconstrictor</p> <p><b>Uses</b></p> <ul style="list-style-type: none"> <li>■ helps relieve the local itching and discomfort associated with hemorrhoids</li> <li>■ temporarily shrinks hemorrhoidal tissue and relieves burning</li> </ul>	<p><b>Drug Facts (continued)</b></p> <ul style="list-style-type: none"> <li>■ temporarily provides a coating for relief of anorectal discomforts</li> <li>■ temporarily protects the inflamed, irritated anorectal surface to help make bowel movements less painful</li> </ul> <p><b>Warnings</b> <b>For external and/or intrarectal use only</b></p> <p>Ask a doctor before use if you have</p> <ul style="list-style-type: none"> <li>■ heart disease</li> <li>■ high blood pressure</li> </ul>	<p><b>Drug Facts (continued)</b></p> <ul style="list-style-type: none"> <li>■ thyroid disease</li> <li>■ diabetes</li> <li>■ difficulty in urination due to enlargement of the prostate gland</li> </ul> <p>Ask a doctor or pharmacist before use if you are presently taking a prescription drug for high blood pressure or depression.</p> <p>When using this product do not exceed the recommended daily dosage unless directed by a doctor</p>	<p><b>Drug Facts (continued)</b></p> <p>Stop use and ask a doctor if</p> <ul style="list-style-type: none"> <li>■ bleeding occurs</li> <li>■ condition worsens or does not improve within 7 days</li> <li>■ introduction of applicator into the rectum causes additional pain</li> </ul> <p>If pregnant or breast-feeding, ask a health professional before use.</p> <p>Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.</p>
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**Drug Facts (continued)**

**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 ointment.
- when first opening the tube, puncture foil seal with tip end of cap
- apply to the affected areas up to 4 times daily, especially at night, in the morning or after each bowel movement



## PREPARATION H

mineral oil, petrolatum, phenylephrine hcl ointment

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:0573-2871
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>PHENYLEPHRINE HYDROCHLORIDE</b> (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	2.5 mg in 1 g
<b>MINERAL OIL</b> (UNII: T5L8T28FGP) (MINERAL OIL - UNII:T5L8T28FGP)	MINERAL OIL	140 mg in 1 g
<b>PETROLATUM</b> (UNII: 4T6H12BN9U) (PETROLATUM - UNII:4T6H12BN9U)	PETROLATUM	749 mg in 1 g

### Inactive Ingredients

Ingredient Name	Strength
<b>BENZOIC ACID</b> (UNII: 8SKN0B0MIM)	
<b>BUTYLATED HYDROXYANISOLE</b> (UNII: REK4960K2U)	
<b>CORN OIL</b> (UNII: 8470G57WFM)	

GLYCERIN (UNII: PDC6A3C0OX)	
LANOLIN (UNII: 7EV65EAW6H)	
LANOLIN ALCOHOLS (UNII: 884C3FA9HE)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PARAFFIN (UNII: I9O0E3H2ZE)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
WATER (UNII: 059QF0KO0R)	
THYME (UNII: CW657OBU4N)	
WHITE WAX (UNII: 7G1J5DA97F)	
TOCOPHEROL (UNII: R0ZB2556P8)	

### Product Characteristics

Color	YELLOW (smooth yellow ointment)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0573-2871-10	1 in 1 CARTON	03/01/2004	
1		28 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:0573-2871-20	1 in 1 CARTON	03/01/2004	
2		57 g in 1 TUBE; Type 0: Not a Combination Product		
3	NDC:0573-2871-04	2 in 1 PACKAGE	03/01/2004	
3		1 in 1 CARTON		
3		57 g in 1 TUBE; Type 0: Not a Combination Product		
4	NDC:0573-2871-91	1 in 1 CARTON	03/01/2018	
4		28 g in 1 TUBE; Type 0: Not a Combination Product		
5	NDC:0573-2871-92	1 in 1 CARTON	03/01/2018	
5		57 g in 1 TUBE; Type 0: Not a Combination Product		
6	NDC:0573-2871-93	1 in 1 CARTON	06/01/2019	
6		28 g in 1 TUBE; Type 0: Not a Combination Product		
7	NDC:0573-2871-94	1 in 1 CARTON	05/17/2020	
7		57 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	03/01/2004	

**Labeler** - Wyeth Consumer Healthcare LLC (828831730)

### Establishment

Name	Address	ID/FEI	Business Operations
PF Consumer Healthcare		203012470	ANALYSIS(0573-2871) , LABEL(0573-2871) , MANUFACTURE(0573-2871) ,

Revised: 5/2020

Wyeth Consumer Healthcare LLC