

**FORMULATION R - phenylephrine hydrochloride, hydrogenate palm kernel oil suppository**  
**G&W Laboratories, Inc.**

*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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**Formulation R™ Hemorrhoidal Suppositories**

**ACTIVE INGREDIENT**

Hard Fat 85.5%  
Phenylephrine HCl 0.25%

**PURPOSE**

- Protectant
- Vasoconstrictor

**USES**

- helps relieve the local itching and discomfort associated with hemorrhoids
- temporarily relieves burning and 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 rectal use only**

**Ask a doctor before use if you have**

- heart disease
- high blood pressure
- thyroid disease
- diabetes
- difficulty in urination due to an enlarged prostate

**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 use more than directed

**Stop use and ask a doctor if**

- symptoms get worse or do not get better in 7 days
- bleeding occurs

**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, clean the affected area by patting or blotting with an appropriate cleansing wipe. Gently dry by patting or blotting with tissue or a soft cloth before insertion of the product.

- remove wrapper before inserting into the rectum as follows:



- hold suppository with pointed end up
  - carefully separate tabs with fingernail
  - slowly pull apart by pulling tabs down on both sides
  - remove suppository from wrapper
- insert one suppository into the rectum up to 4 times daily, especially at night, in the morning or after each bowel movement
  - children under 12 years: ask a doctor

## **OTHER INFORMATION**

- store at 20-25°C (68-77°F)

## **INACTIVE INGREDIENT**

cod liver oil, corn starch, methylparaben, propylparaben

## **PACKAGE LABEL.PRINCIPAL DISPLAY PANEL**

NDC 0713-0535-24

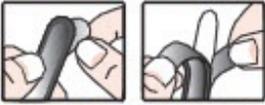
G&W Formulation R™ HEMORRHOIDAL SUPPOSITORIES

Prompt Soothing Relief from Painful Burning, Itching and Discomfort

24 ADULT SUPPOSITORIES

Tamper-Evident: For your safety suppositories are packaged in "Tamper-Evident" sealed foil. Do not use if foil is torn or open

Compare to active ingredients in Preparation-H® Hemorrhoidal Suppositories  
FOR TEMPORARY RELIEF FROM PAIN AND ITCHING OF HEMORRHOIDS

<p><b>Drug Facts</b> (continued)</p> <p><b>Warnings</b></p> <p><b>For rectal use only</b></p> <p><b>Ask a doctor before use if you have</b></p> <ul style="list-style-type: none"> <li>heart disease</li> <li>high blood pressure</li> <li>thyroid disease</li> <li>diabetes</li> <li>difficulty in urination due to an enlarged prostate</li> </ul> <p><b>Ask a doctor or pharmacist before use if you are</b> presently taking a prescription drug for high blood pressure or depression</p> <p><b>When using this product</b> • do not use more than directed</p> <p><b>Stop use and ask a doctor if</b></p> <ul style="list-style-type: none"> <li>symptoms get worse or do not get better in 7 days</li> <li>bleeding occurs</li> </ul> <p><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></p> <ul style="list-style-type: none"> <li>adults: when practical, clean the affected area by patting or blotting with an appropriate cleansing wipe. Gently dry by ▶</li> </ul>	<p><b>Drug Facts</b> (continued)</p> <p>patting or blotting with tissue or a soft cloth before insertion of the product.</p> <ul style="list-style-type: none"> <li>remove wrapper before inserting into the rectum as follows:</li> </ul>  <ul style="list-style-type: none"> <li>hold suppository with pointed end up</li> <li>carefully separate tabs with fingernail</li> <li>slowly pull apart by pulling tabs down on both sides</li> <li>remove suppository from wrapper</li> </ul> <ul style="list-style-type: none"> <li>Insert one suppository into the rectum up to 4 times daily, especially at night, in the morning or after each bowel movement</li> <li>children under 12 years: ask a doctor</li> </ul> <p><b>Other Information</b></p> <ul style="list-style-type: none"> <li>store at 20-25°C (68-77°F)</li> </ul> <p><b>Inactive Ingredients:</b> cod liver oil, corn starch, methylparaben, propylparaben</p>
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\*This product is not manufactured or distributed by Wyeth Consumer Healthcare, owner of the registered trademark Preparation H®.

Manufactured By:  
G&W Laboratories, Inc.  
111 Coolidge Street  
South Plainfield, NJ 07080  
Visit our website @ [www.gwlab.com](http://www.gwlab.com)

N3-0713-0535-24

<p>Tamper-Evident: For your safety suppositories are packaged in "Tamper-Evident" sealed foil. Do not use if foil is torn or open</p>  <p><b>Formulation R™</b></p> <p><b>HEMORRHOIDAL SUPPOSITORIES</b></p> <p>Prompt Soothing Relief from Painful Burning, Itching and Discomfort</p> <p><b>24 ADULT SUPPOSITORIES</b></p>	<p>NDC 0713-0535-24</p> <p>*Compare to active ingredients in Preparation-H® Hemorrhoidal Suppositories</p> <p><b>FOR TEMPORARY RELIEF FROM PAIN AND ITCHING OF HEMORRHOIDS</b></p> 
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<p><b>Drug Facts</b></p> <table border="1"> <thead> <tr> <th>Active Ingredients (in each rectal suppository)</th> <th>Purpose</th> </tr> </thead> <tbody> <tr> <td>Hard Fat 85.5%.....</td> <td>Protectant</td> </tr> <tr> <td>Phenylephrine HCl 0.25%.....</td> <td>Vasoconstrictor</td> </tr> </tbody> </table>	Active Ingredients (in each rectal suppository)	Purpose	Hard Fat 85.5%.....	Protectant	Phenylephrine HCl 0.25%.....	Vasoconstrictor	<p><b>Drug Facts</b> (continued)</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 relieves burning and shrinks hemorrhoidal tissue</li> <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>
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<b>FORMULATION R</b>			
phenylephrine hydrochloride, hydrogenate palm kernel oil suppository			
<b>Product Information</b>			
<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:0713-0535
<b>Route of Administration</b>	RECTAL		
<b>Active Ingredient/Active Moiety</b>			

Ingredient Name	Basis of Strength	Strength
<b>Phenylephrine Hydrochloride</b> (UNII: 04JA59TNSJ) (Phenylephrine - UNII:1WS297W6MV)	Phenylephrine Hydrochloride	2.5 mg
<b>Hydrogenated Palm Kernel Oil</b> (UNII: FM8D1RE2VP) (Hydrogenated Palm Kernel Oil - UNII:FM8D1RE2VP)	Hydrogenated Palm Kernel Oil	855 mg

### Inactive Ingredients

Ingredient Name	Strength
<b>Cod Liver Oil</b> (UNII: BBL281NWFG)	
<b>Starch, Corn</b> (UNII: O8232NY3SJ)	
<b>Methylparaben</b> (UNII: A2I8C7HI9T)	
<b>Propylparaben</b> (UNII: Z8IX2SC1OH)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0713-0535-24	24 in 1 CARTON		
2	NDC:0713-0535-12	12 in 1 CARTON		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part346	06/24/2002	

**Labeler** - G&W Laboratories, Inc. (001271188)

**Registrant** - G&W Laboratories, Inc. (001271188)

### Establishment

Name	Address	ID/FEI	Business Operations
G&W Laboratories, Inc.		001271188	MANUFACTURE

Revised: 1/2012

G&W Laboratories, Inc.