

**HEMORRHOIDAL RELIEF CREAM- lidocane and glycerin cream**  
**CVS Pharmacy, 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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**CVS Health Hemorrhoidal Cream Maximum Strength Lidocaine Formula**

Uses

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

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 6 times daily, especially at night, in the morning or after each bowel movement.
- Children under 12 years of age, ask a doctor

Inactive ingredients: Aloe Barbadosensis Leaf Juice, Benzyl Alcohol, Carbomer, Cholesterol, Hydrogenated Lecithin, Isopropyl Myristate, Polysorbate 80, Purified Water, Triethanolamine, vitamin E Acetate

Active Ingredients Purpose

Lidocaine 5%.....Local anesthetic

Glycerin 14.4%.....Protectant

Protectant

Local anesthetic

Keep out of reach of children. If swallowed get medical help or contact a Poison Control Center right away.

If pregnant or breast-feeding

- Ask a health professional before use.

Stop use and ask a doctor if

- Rectal bleeding occurs
- Condition worsens or does not improve within 7 days
- An allergic reaction occurs

- The symptom being treated does not subside or if redness, irritation, swelling, pain, or other symptoms develop or increase

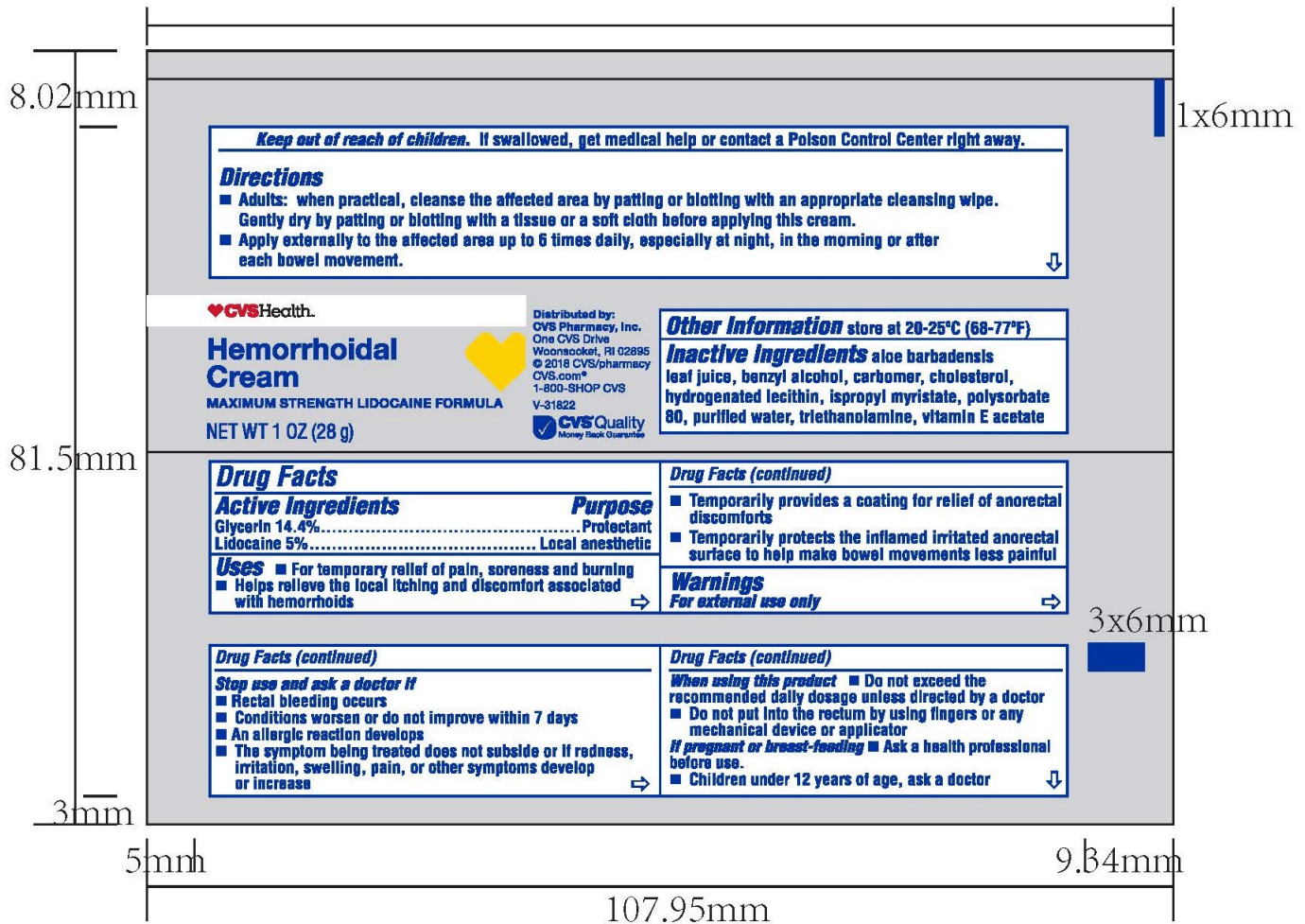
Ask a doctor or pharmacist before use if you are presently taking a prescription drug for high blood pressure or depression.

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

When using this product

- Do not exceed the recommended daily dosage unless directed by a doctor
- Do not put this product into the rectum by using fingers or any mechanical device or applicator

<p><b>Drug Facts (continued)</b></p> <ul style="list-style-type: none"> <li>Children under 12 years of age, ask a doctor</li> </ul> <p><b>Other information</b> store at 20-25°C (68-77°F)</p> <p><b>Inactive ingredients</b> also benzocaine leaf juice, benzyl alcohol, carbomer, cholesterol, hydrogenated lecithin, lauryl myristate, polysorbate 80, purified water, triethanolamine, vitamin E acetate</p>	<p>Distributed by: CVS Pharmacy, Inc. One CVS Drive, Woonsocket, RI 02896 © 2018 CVS Pharmacy CVS.com® 1-800-8HOP CVS V-31422</p> <p><b>CVS Quality</b> Money Back Guarantee</p> <p>*This product is not manufactured or distributed by Pfizer, distributor of Preparation H® Rapid Relief Hemorrhoidal Cream with Lidocaine.</p> <p>#255249</p>  <p>0 50428 44340 8</p>				
<p><b>CVS Health.</b> Compare to the active ingredients in Preparation H® Rapid Relief Hemorrhoidal Cream with Lidocaine®</p> <p><b>Hemorrhoidal Cream</b></p> <p><b>MAXIMUM STRENGTH LIDOCAINE FORMULA</b></p> <ul style="list-style-type: none"> <li>• Prompt numbing relief from painful burning, itching &amp; discomfort</li> <li>• Shrinks swollen hemorrhoidal tissue</li> <li>• Protects irritated tissue with soothing barrier layer</li> <li>• Relieves internal &amp; external discomfort</li> </ul> <p>NET WT 1 OZ (28 g)</p> 					
<p><b>Drug Facts</b></p> <p><b>Active Ingredients</b></p> <table border="0"> <tr> <td>Eiparin 14.4%</td> <td>Prolactant</td> </tr> <tr> <td>Lidocaine 5%</td> <td>Local anesthetic</td> </tr> </table> <p><b>Uses</b></p> <ul style="list-style-type: none"> <li>• For temporary relief of pain, soreness and burning</li> <li>• Helps relieve the local itching and discomfort associated with hemorrhoids</li> </ul>	Eiparin 14.4%	Prolactant	Lidocaine 5%	Local anesthetic	<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></p> <p>For external use only</p>
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<p><b>Drug Facts (continued)</b></p> <p><b>Stop use and ask a doctor if</b></p> <ul style="list-style-type: none"> <li>• Rectal bleeding occurs</li> <li>• Conditions worsen or do not improve within 7 days</li> <li>• An allergic reaction develops</li> <li>• The symptom being treated does not subside or if redness, irritation, swelling, pain, or other symptoms develop or increase</li> </ul> <p><b>When using this product</b></p> <ul style="list-style-type: none"> <li>• Do not exceed the recommended daily dosage unless directed by a doctor</li> <li>• Do not put into the rectum by using fingers or any mechanical device or applicator</li> </ul> <p><b>If pregnant or breast-feeding</b> Ask a health professional before use.</p>	<p><b>Drug Facts (continued)</b></p> <p><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, 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.</li> <li>• Apply externally in the affected area up to 6 times daily, especially at night, in the morning or after each bowel movement.</li> </ul>				
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## HEMORRHOIDAL RELIEF CREAM

lidocaine and glycerin cream

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:51316-333
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>GLYCERIN</b> (UNII: PDC6A3C0OX) (GLYCERIN - UNII:PDC6A3C0OX)	GLYCERIN	4.032 g in 28 g
<b>LIDOCAINE</b> (UNII: 98PI200987) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE	1.4 g in 28 g

### Inactive Ingredients

Ingredient Name	Strength
<b>ALOE VERA LEAF</b> (UNII: ZY81Z83H0X)	
<b>BENZYL ALCOHOL</b> (UNII: LKG8494WBH)	
<b>CARBOMER HOMOPOLYMER TYPE C</b> (UNII: 4Q93RCW27E)	
<b>CHOLESTEROL</b> (UNII: 97C5T2UQ7J)	

<b>HYDROGENATED SOYBEAN LECITHIN</b> (UNII: H1109Z9J4N)	
<b>ISOPROPYL MYRISTATE</b> (UNII: 0RE8K4LNJS)	
<b>POLYSORBATE 80</b> (UNII: 6OZP39ZG8H)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>ALPHA-TOCOPHEROL ACETATE</b> (UNII: 9E8X80D2L0)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51316-333-01	1 in 1 BOX	09/08/2021	
1	NDC:51316-333-28	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	09/08/2021	

**Labeler** - CVS Pharmacy, Inc (062312574)

**Registrant** - Melaleuca, Inc. (139760102)

### Establishment

Name	Address	ID/FEI	Business Operations
Melaleuca, Inc.		805617610	manufacture(51316-333)

Revised: 10/2021

CVS Pharmacy, Inc