

HEMORRHOIDAL- glycerin, lidocaine cream
VELOCITY PHARMA 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.

Hemorrhoidal cream Rapid Relief with Lidocaine

Drug Facts

<i>Active ingredients</i>	<i>Purposes</i>
Glycerin 14.4%	Protectant
Lidocaine 5%	Local anesthetic

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

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

- rectal 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 6 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 vera gel, anhydrous citric acid, butylated hydroxyanisole, carboxymethylcellulose sodium, cetyl

alcohol, citric acid monohydrate, edetate disodium, glyceryl monostearate, methylparaben, mineral oil, polyoxyl lauryl ether, polyoxyl stearyl ether, propylene glycol, propylparaben, purified water, stearyl alcohol, white soft paraffin, xanthan gum

Questions or comments?

Call 888-309-9030

PRINCIPAL DISPLAY PANEL



HEMORRHOIDAL			
glycerin, lidocaine cream			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:76 168 -403
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

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)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
MINERAL OIL (UNII: T5L8T28FGP)	
LAURETH-23 (UNII: N72LMW566G)	
PETROLATUM (UNII: 4T6HI2BN9U)	
STEARETH-2 (UNII: V56DFE46J5)	
STEARETH-20 (UNII: L0Q8IK9E08)	
PROPYL GALLATE (UNII: 8D4SNN7V92)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
WATER (UNII: 059QF0K00R)	
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:76168-403-01	1 in 1 CARTON	06/04/2019	
1		30 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	06/04/2019	

Labeler - VELOCITY PHARMA LLC (962198409)