

**REVIVOL HEMORRHOID AND FISSURE- glycerin 14.4%, lidocaine 5%, petrolatum 15%, phenylephrine hcl 0.25% cream  
Derma Care Research Labs, 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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**Revivol Hemorrhoid and Fissure Cream**

Glycerin 14.4%, Lidocaine 5%, Petrolatum 15%, Phenylephrine HCl 0.25%

Anorectal/Hemorrhoidal

For the 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 the relief of anorectal discomforts. Temporarily protects the inflamed, irritated anorectal surface to help make bowel movements less painful.

**For external and/or intrarectal use.**

**Ask a doctor before use if you have:** heart disease, high blood pressure, thyroid disease, diabetes, or 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 recommended dosage unless directed by a doctor.

**Stop use and ask a doctor if** condition worsens or does not improve within seven (7) days, bleeding occurs, an allergic reaction develops, the symptom being treated does not subside or if redness, irritation, swelling, pain or other symptoms develop or increase.

Ask a health care professional before use.


If swallowed, seek medical help or contact a Poison Control Center right away.

Adults: when practical, cleanse area with mild soap and warm water and rinse thoroughly. Gently dry by patting or blotting with toilet tissue or soft cloth before applying. Apply externally to the affected area up to 4 times daily, especially at night, in the morning or after each bowel movement. Children under 12 years of age: consult a doctor.

For intrarectal use: attach applicator to tube. Lubricate well, then gently insert applicator into the rectum. Thoroughly cleanse applicator after use with mild soap and warm water and rinse thoroughly.

Aesculus hippocastanum (horse chestnut) extract, aloe barbadensis leaf extract, BHA, calendula officinalis extract, cellulose gum, centella asiatica extract, cetyl alcohol, citric acid, disodium EDTA, ethylhexylglycerin, glyceryl stearate, hamamelis virginiana (witch hazel) leaf extract, mineral oil, panthenol, phenoxyethanol, propyl gallate, propylene glycol, sorbitan olivate, steareth-21, stearyl alcohol, tocopherol, tocopheryl acetate,

water, xanthan gum.




**5% Lidocaine + Natural Soothing Botanical Extracts** NDC 72839-295-01  
 + 0.25% Phenylephrine HCl + 15% Petrolatum + 14.4% Glycerin

**ADVANCED FORMULA**

# Hemorrhoid & Fissure Cream

**Rapid Relief from Pain, Burn, Itch and Swelling Associated with Inflamed Rectal Tissue**

NET WT 1.5 OZ (42.5g)



**Drug Facts** (continued)

**Directions** • adults: when practical, cleanse area with mild soap and warm water and rinse thoroughly. Gently dry by patting or blotting with toilet tissue or soft cloth before applying

- apply externally to the affected area up to 4 times daily, especially at night, in the morning or after each bowel movement
- children under 12 years of age: consult a doctor
- for intrarectal use: attach applicator to tube. Lubricate applicator well, then gently insert applicator into the rectum. Thoroughly cleanse applicator after use with mild soap and warm water and rinse thoroughly.

**Other information** • store at 15°-30°C (59° to 86°F) ▶

**Drug Facts** (continued)

**Inactive ingredients**  
 aesculus hippocastanum (horse chestnut) extract, aloe barbadensis leaf extract, BHA, calendula officinalis extract, cellulose gum, centella asiatica extract, cetyl alcohol, citric acid, disodium EDTA, ethylhexylglycerin, glyceryl stearate, hamamelis virginiana (witch hazel) leaf extract, mineral oil, panthenol, phenoxyethanol, propyl gallate, propylene glycol, sorbitan olivate, steareth-21, stearyl alcohol, tocopheryl acetate, water, xanthan gum

 **Made in the U.S.A.**  
 with Domestic & International Components



SCAN NOW

Learn How To Use & Get Your Best Results.

[www.hemorrhoid.com](http://www.hemorrhoid.com)  
[info@hemorrhoid.com](mailto:info@hemorrhoid.com)

Distributed by:  
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 West Palm Beach, FL 33411 • (561) 247-5134

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1.5 OZ (42.5g)



**ADVANCED FORMULA**

# Hemorrhoid & Fissure Cream

**Rapid Relief from Pain, Burn, Itch and Swelling Associated with Inflamed Rectal Tissue**

**5% Lidocaine**  
 + 0.25% Phenylephrine HCl  
 + 15% Petrolatum  
 + 14.4% Glycerin  
 + Natural Soothing Botanical Extracts

NDC 72839-295-01

**Drug Facts**

Active ingredients	Purpose
Glycerin 14.4%	Protectant
Lidocaine 5%	Analgesic (pain relief)
Petrolatum 15%	Protectant
Phenylephrine HCl 0.25%	Vasoconstrictor

**Uses**

- temporarily protects the inflamed, irritated anorectal surface to help make bowel movements less painful from irritation and abrasion during bowel movement
- for the temporary relief of pain, soreness, or burning ▶

**Drug Facts** (continued)

- helps relieve the local or anorectal itching and discomfort associated with hemorrhoids

**Warnings**  
**For external and/or intrarectal use**

**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 ▶

**Drug Facts** (continued)

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

**Stop use and ask a doctor if** • introduction of applicator into the rectum causes additional pain • condition worsens or does not improve within seven (7) days • bleeding occurs • 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 care professional before use. **Keep out of reach of children.** If swallowed, seek medical help or contact a Poison Control Center right away. ▼

**REVIVOL HEMORRHOID AND FISSURE**  
 glycerin 14.4%, lidocaine 5%, petrolatum 15%, phenylephrine hcl 0.25% cream

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:72839-295
<b>Route of Administration</b>	TOPICAL		

## Active Ingredient/Active Moiety

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<b>LIDOCAINE</b> (UNII: 98PI200987) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE	5 g in 100 g
<b>PETROLATUM</b> (UNII: 4T6H12BN9U) (PETROLATUM - UNII:4T6H12BN9U)	PETROLATUM	15 g in 100 g
<b>GLYCERIN</b> (UNII: PDC6A3C0OX) (GLYCERIN - UNII:PDC6A3C0OX)	GLYCERIN	14.4 g in 100 g
<b>PHENYLEPHRINE HYDROCHLORIDE</b> (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE	0.25 g in 100 g

## Inactive Ingredients

<b>Ingredient Name</b>	<b>Strength</b>
<b>CALENDULA OFFICINALIS FLOWER</b> (UNII: P0M7O4Y7YD)	
<b>HAMAMELIS VIRGINIANA LEAF</b> (UNII: T07U1161SV)	
<b>HORSE CHESTNUT</b> (UNII: 3C18L6RJAZ)	
<b>CENTELLA ASIATICA TRITERPENOIDS</b> (UNII: 4YS74Q4G4J)	
<b>MINERAL OIL</b> (UNII: T5L8T28FGP)	
<b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)	
<b>.ALPHA.-TOCOPHEROL ACETATE</b> (UNII: 9E8X80D2L0)	
<b>XANTHAN GUM</b> (UNII: TTV12P4NEE)	
<b>CETYL ALCOHOL</b> (UNII: 936JST6JCN)	
<b>CITRIC ACID MONOHYDRATE</b> (UNII: 2968PHW8QP)	
<b>EDETATE DISODIUM</b> (UNII: 7FLD91C86K)	
<b>PANTHENOL</b> (UNII: WW9CM0067Z)	
<b>BUTYLATED HYDROXYANISOLE</b> (UNII: REK4960K2U)	
<b>ALOE VERA LEAF</b> (UNII: ZY81Z83H0X)	
<b>SORBITAN OLIVATE</b> (UNII: MDL271E3GR)	
<b>STEARETH-21</b> (UNII: 53J3F32P58)	
<b>WATER</b> (UNII: 059QF0K00R)	
<b>ETHYLHEXYLGLYCERIN</b> (UNII: 147D247K3P)	
<b>GLYCERYL MONOSTEARATE</b> (UNII: 230OU9XXE4)	
<b>PROPYL GALLATE</b> (UNII: 8D45NN7V92)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>CARBOXYMETHYLCELLULOSE SODIUM</b> (UNII: K679OBS311)	
<b>STEARYL ALCOHOL</b> (UNII: 2KR89I4H1Y)	
<b>TOCOPHEROL</b> (UNII: ROZB2556P8)	

## Packaging

<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:72839-295-01	1 in 1 CARTON	05/12/2023	

1	42.5 g in 1 TUBE; Type 0: Not a Combination Product		
<b>Marketing Information</b>			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	M015	05/12/2023	

**Labeler** - Derma Care Research Labs, LLC (116817470)

**Registrant** - Derma Care Research Labs, LLC (116817470)

<b>Establishment</b>			
Name	Address	ID/FEI	Business Operations
Derma Care Research Labs, LLC		116817470	manufacture(72839-295)

Revised: 7/2023

Derma Care Research Labs, LLC