

DCH HEMORRHOIDAL- 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.

DCH Hemorrhoidal Pain Relief 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 use only.

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: avoid contact with eyes, do not exceed recommended dosage unless directed by a doctor, do not put this product into 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 seven (7) days, allergic reaction occurs to ingredients in this product, symptom being treated does not subside or if redness, irritation, swelling, pain or other symptoms develop or increase, symptoms clear up and return within a few days.

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. Adults and children 12 years and older: apply externally to the affected area up to 4 times a day. Children under 12 years of age: consult a doctor.

Aloe barbadensis leaf extract, BHA, cellulose gum, cetyl alcohol, citric acid, disodium EDTA, ethylhexylglycerin, glyceryl stearate, mineral oil, panthenol, Phenoxyethanol, propyl gallate, propylene glycol, sorbitan olivate, steareth-21, stearyl alcohol, tocopherol, tocopheryl acetate, water, xanthan gum.



Rapid Pain Relief Hemorrhoidal Cream

Maximum Strength

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

Rapid numbing relief of pain, itching & burning

Reduces swelling & provides a soothing protective layer



* Compare to active ingredients in Preparation H® Rapid Relief
Net Wt. 1 oz (28 g)

Drug Facts (continued)

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

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 • adults and children 12 years and older: apply externally to the affected area up to 6 times a day • children under 12 years of age: consult a doctor.

Drug Facts (continued)

Other information
store at 15° - 30°C (59° - 86°F)

Inactive ingredients aloe barbadensis leaf extract, BHA, cellulose gum, cetyl alcohol, citric acid, disodium EDTA, ethylhexylglycerin, glyceryl stearate, mineral oil, panthenol, phenoxyethanol, propyl gallate, propylene glycol, sorbitan olivate, steareth-21, stearyl alcohol, tocopherol, tocopheryl acetate, water, xanthan gum

* This product is not manufactured or distributed by GSK Consumer Healthcare Holdings (US) LLC, owner of the registered trademark Preparation H ©.

Manufactured by:
DermaCare Research Labs, LLC
440 Fentress Blvd., Daytona Beach, FL 32114



DCH LABS



Rapid Pain Relief Hemorrhoidal Cream

Maximum Strength

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

- Rapid numbing relief of pain, itching & burning
- Reduces swelling & provides a soothing protective layer

* Compare to active ingredients in Preparation H® Rapid Relief
Net Wt. 1 oz (28 g)

Drug Facts (continued)

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 • avoid contact with eyes • do not exceed recommended dosage unless directed by a doctor • do not put this product into 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 seven (7) days • allergic reaction occurs to ingredients in this product • symptom being treated does not subside or if

Drug Facts (continued)

- temporarily provides a coating for the relief of anorectal discomforts
- temporarily protects the inflamed, irritated anorectal surface to help make bowel movements less painful

Warnings
For external 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

Drug Facts

Active ingredients

- Lidocaine 5%.....Local anesthetic
- Glycerin 14.4%.....Protectant
- Petrolatum 15%.....Protectant
- Phenylephrine HCl 0.25%.....Vasoconstrictor

Uses

- for the temporary relief of pain, soreness, and burning with hemorrhoids
- helps relieve the local itching and discomfort associated with hemorrhoids
- temporarily shrinks hemorrhoidal tissue

DCH HEMORRHOIDAL

glycerin 14.4%, lidocaine 5%, petrolatum 15%, phenylephrine hcl 0.25% cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:72839-217
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
MINERAL OIL (UNII: T5L8T28FGP)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
XANTHAN GUM (UNII: TTV12P4NEE)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
PANTHENOL (UNII: WW9CM0O67Z)	
BUTYLATED HYDROXYANISOLE (UNII: REK4960K2U)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
SORBITAN OLIVATE (UNII: MDL271E3GR)	
STEARETH-21 (UNII: 53J3F32P58)	
WATER (UNII: 059QF0KO0R)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
PROPYL GALLATE (UNII: 8D45NN7V92)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311)	
STEARYL ALCOHOL (UNII: 2KR89I4H1Y)	
TOCOPHEROL (UNII: ROZB2556P8)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72839-217-01	1 in 1 CARTON	05/12/2023	
1		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	M015	05/12/2023	

Labeler - Derma Care Research Labs, LLC (116817470)

Registrant - Derma Care Research Labs, LLC (116817470)

Establishment

Name	Address	ID/FEI	Business Operations
Derma Care Research Labs, LLC		116817470	manufacture(72839-217)

Revised: 7/2023

Derma Care Research Labs, LLC