

DERMATOOL 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.

Dermatool Hemorrhoidal 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.

Aesculus hippocastanum (horse chestnut) extract, aloe barbadensis leaf extract, BHA, cellulose gum, 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.

<p>Drug Facts (continued)</p> <p>Ask a doctor or pharmacist before use if you are presently taking a prescription drug for high blood pressure or depression</p> <p>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</p> <p>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</p>	<p>Drug Facts (continued)</p> <p>• temporarily provides a coating for the relief of anorectal discomforts</p> <p>• temporarily protects the inflamed, irritated anorectal surface to help make bowel movements less painful</p> <p>Warnings</p> <p>For external use only</p> <p>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</p>	<p>Drug Facts</p> <p>Active ingredients</p> <p>Protectant 14.4% Glycerin 5% Lidocaine 5% Petrolatum 15% Phenylephrine HCl 0.25% Vasoconstrictor</p> <p>Uses</p> <ul style="list-style-type: none"> • 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
--	---	--

DERMATOOL®

HEMORRHOIDAL CREAM

ADVANCED RAPID RELIEF FORMULA

5% HIGHEST STRENGTH LIDOCAINE & PHENYLEPHRINE HCl AVAILABLE

Rapid Numbing Relief of Pain, Itching & Burning
Reduces Swelling & Provides a Soothing Protective Layer

Medicated Treatment Enhanced With:
Witch Hazel, Aloe, Vitamin E & Natural Ingredients

LIDOCAINE • PHENYLEPHRINE HCl
GLYCERIN • PETROLATUM

1 TUBE | NET WT 1.5 OZ (42.5g)

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 4 times a day • children under 12 years of age: consult a doctor.

Drug Facts (continued)

Other information
store at 20° - 25°C (68° - 77°F)

Inactive ingredients
Aesculus Hippocastanum (Horse Chestnut) Extract, Aloe Barbadensis Leaf Extract, BHA, Cellulose Gum, Cetyl Alcohol, Citric Acid, Disodium EDTA, Ethylhexylglycerin, Glycerin Stearate, Hamamelis Virginiana (Witch Hazel) Leaf Extract, Mineral Oil, Panthenol, Phenoxyethanol, Propyl Gallate, Propylene Glycol, Sorbitan Oliviate, Steareth-21, Stearyl Alcohol, Tocopherol, Tocopheryl Acetate, Water, Xanthan Gum

Questions?
email us at support@dermatoolcare.com

DISTRIBUTED BY: Dermatool®
Hoboken, NJ 07030
www.dermatoolcare.com

Made in the U.S.A with domestic and foreign components

 MADE IN USA



LIDOCAINE • PHENYLEPHRINE HCl • GLYCERIN • PETROLATUM

1 TUBE | NET WT 1.5 OZ (42.5g)

DERMATOOL®
HEMORRHOIDAL CREAM
ADVANCED RAPID RELIEF FORMULA

- 5% HIGHEST STRENGTH LIDOCAINE & PHENYLEPHRINE HCl AVAILABLE
- Rapid Numbing Relief of Pain, Itching & Burning
- Reduces Swelling & Provides a Soothing Protective Layer
- Medicated Treatment Enhanced With: Witch Hazel, Aloe, Vitamin E & Natural Ingredients

DERMATOOL HEMORRHOIDAL

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

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:72839-413
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
HORSE CHESTNUT (UNII: 3C18L6RJAZ)	
HAMAMELIS VIRGINIANA LEAF (UNII: T07U1161SV)	
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)	
BUTYLATED HYDROXYANISOLE (UNII: REK4960K2U)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
SORBITAN OLIVATE (UNII: MDL271E3GR)	
STEARETH-21 (UNII: 53J3F32P58)	
WATER (UNII: 059QF0KOOR)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
PANTHENOL (UNII: WW9CM0O67Z)	
PROPYL GALLATE (UNII: 8D4SNN7V92)	
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:72839-413-01	1 in 1 CARTON	05/10/2023	
1		42.5 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	05/10/2023	

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(72839-413)

Revised: 5/2023

Derma Care Research Labs, LLC