DR. BUTLER HEMORRHOID TREATMENT- phenylephrine hydrochloride 0.25%, witch hazel 50% spray

Beyond Health P.A.

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.

Hemorrhoid Treatment Spray

Phenylephrine HCl 0.25%, Witch Hazel 50%

Vasoconstrictor, Astringent

Temporarily reduces swelling associated with hemorrhoidal tissue. Temporary relief of anorectal itching and discomfort associated with hemorrhoids and other anorectal disorders.

For external use only.

When using this product avoid spraying in eyes, contents under pressure. Do not puncture or incinerate. Do not store at temperatures above 120F, do not exceed recommended daily dosage unless directed by a doctor, do not put this product in the rectum by using fingers or any mechanical device or applicator.

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, presently taking a prescription for high blood pressure or depression.

Stop use and ask a doctor if bleeding occurs, the condition worsens, symptoms last more than 7 days or clear up and occur again within a few days, needed for longer than 1 week.

Ask a healthcare or professional before use.

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

Adults: when practical, cleanse the affected area by patting or blotting with Doctor Butler's Soothing Organic Wipes. Spray the rectal area until thoroughly moist. Wipe off excess with a tissue, gently dry by patting or blotting with a tissue or a soft cloth, apply 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.

Alcohol 7%, Aloe Barbadensis Leaf Extract, Benzophenone-4, Disodium EDTA, Hydroxyethylcellulose, Methylparaben, Polysorbate 80, Propylene Glycol, Propylparaben, Sodium Citrate, Tocopheryl Acetate, Water.



"Leave the Pain Behind"™

HEMORRHOID TREATMENT SPRAY

with WITCH HAZEL

RELIEVES:

Discomfort • Itching • Swelling **Associated with Irritated & Inflammed** Hemorrhoids

Contains FDA Approved Ingredients As Well As Herbal Extracts*

FREE FROM:

Butane • Propellants • Fragrance • Dyes

No Touch Precise Application



Net Wt 3.0 OZ (85 g)

Drug Facts

Active ingredients

Purpose

Phenylephrine HCI 0.25%.... Witch Hazel 50%.

Vasoconstrictor .Astringent

Uses ■ temporarily reduces swelling associated with hemorrhoidal tissue ■ temporary relief of anorectal itching and discomfort associated with hemorrhoids and other anorectal disorders

Warnings For external use only.

When using this product ■ avoid spraying in eyes ■ contents under pressure. Do not puncture or incinerate. Do not store at temperatures above 120°F ■ 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.

Ask a doctor or pharmacist before use if you have ■ heart disease, high blood pressure, thyroid disease, diabetes, difficulty in urination due to enlargement of the prostate gland • are presently taking a prescription drug for high blood pressure or depression.

Stop use and ask a doctor if - bleeding occurs - condition worsens symptoms last more than 7 days or clears up and occurs again within a few days - needed for longer than 1 week.

If pregnant or breastfeeding ask a healthcare professional before use.

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

Directions Adults: ■ when practical, cleanse the affected area by patting or blotting with Doctor Butler's Soothing Organic Wipes ■ spray rectal area until thoroughly moist. Wipe off excess with tissue ■ gently dry by patting or blotting with a tissue or a soft cloth ■ apply 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.

Other information - Store between 15°-30°C (59°-86°F)

Inactive ingredients Aloe Barbadensis Leaf Extract, Benzophenone-4, Disodium EDTA, Hydroxyethylcellulose, Methylparaben, Polysorbate 80, Propylene Glycol, Propylparaben, Sodium Citrate, Tocopheryl Acetate, Water.

Active ingredients compliant with FDA Monograph Title 21, Part 346.

Cruelty Free - No Animal Testing

Distributed by: Beyond Health P.A. Tequesta, FL 33469 Phone: (561) 935-9698

Made in the U.S.A. www.DoctorButlers.com





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DR. BUTLER HEMORRHOID TREATMENT

phenylephrine hydrochloride 0.25%, witch hazel 50% spray

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:70942-811

Route of Administration TOPICAL

Active Ingredient/Active Majety

reave ingredient withery			
Ingredient Name	Basis of Strength	Strength	
WITCH HAZEL (UNII: 10 114J0 U34) (WITCH HAZEL - UNII:10 114J0 U34)	WITCH HAZEL	50 g in 100 g	

PHENYLEPHRINE HYDRO CHLO RIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE	-
IINII-1WS 29 7W6 MV)	

PHENYLEPHRINE

0.25 g in 100 g

Inactive Ingredients	
Ingredient Name	Strength
ALOE (UNII: V5VD430 YW9)	
METHYLPARABEN (UNII: A218 C7HI9 T)	
ALCOHOL (UNII: 3K9958V90M)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
SULISOBENZONE (UNII: 1W6L629B4K)	
EDETATE DISO DIUM (UNII: 7FLD91C86K)	
HYDROXYETHYL CELLULOSE, UNSPECIFIED (UNII: T4V6TWG28D)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
.ALPHATO COPHEROL ACETATE (UNII: 9E8X80D2L0)	
POLYSORBATE 80 (UNII: 6 OZP39 ZG8 H)	
WATER (UNII: 059QF0KO0R)	

ı	Packaging			
ı	# Item Code	Package Description	Marketing Start Date	Marketing End Date
ı	1 NDC:70942-811-03	85 g in 1 CAN; Type 0: Not a Combination Product	12/07/2020	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part346	12/07/2020	

Labeler - Beyond Health P.A. (026781064)

Registrant - Derma Care Research Labs (116817470)

Establishment			
Name	Address	ID/FEI	Business Operations
Derma Care Research Labs		116817470	manufacture (70942-811)

Revised: 12/2020 Beyond Health P.A.