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.

Doctor Butler's 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 with mild soap and warm water and pat dry. 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. For children under 12 years of age, consult a doctor.

Alcohol, Aloe Barbadensis Leaf Extract, Benzophenone-4, Benzyl Alcohol, Disodium EDTA, Ethylhexylglycerin, Hydroxyethylcellulose, Polysorbate 80, Propylene Glycol, Propylparaben, Sodium Citrate, Tocopherol, Tocopheryl Acetate, Water.



DR. BUTLER HEMORRHOID TREATMENT

phenylephrine hydrochloride 0.25%, witch hazel 50% spray

Product Information					
Product Type	HUMAN OTC DRUG	Item Code (Sour	ce)	NDC:70)942-135
Route of Administration	TOPICAL				
Active Ingredient/Active	Moiety				
	gredient Name		Basis Streng		Strength
WITCH HAZEL (UNII: 10114J0U34)	(WITCH HAZEL - UNII:1014	4J0U34)	WITCH HAZE	EL	50 g in 100 g
PHENYLEPHRINE HYDROCHLOP UNII:1WS297W6MV)	RIDE (UNII: 04JA59TNSJ) (PH	IENYLEPHRINE -	PHENYLEPH	RINE	0.25 g in 100 g
Inactive Ingredients					
	Ingredient Name	e			Strength
SULISOBENZONE (UNII: 1W6L629	9В4К)				
ETHYLHEXYLGLYCERIN (UNII: 14	(קצאדו/כחדו				

ALOE (UNII: V5VD430YW9)	
ALCOHOL (UNII: 3K9958V90M)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
HYDROXYETHYL CELLULOSE, UNSPECIFIED (UNII: T4V6TWG28D)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
.ALPHATOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
POLYSORBATE 80 (UNII: 60ZP39ZG8H)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	ltem Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:70942-135- 03	1 in 1 CARTON	12/10/2021		
1		85 g in 1 CAN; Type 0: Not a Combination Product			
Marketing Information					
	Marketing	Application Number or Monograph	Marketing Start	Marketing End	

Category	Citation	Date	Date
OTC monograph final	part346	12/10/2021	

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(70942-135)

Revised: 12/2021

Beyond Health P.A.