DRS. PHARMACY HEMORRHOIDAL COOLING- phenylephrine hcl, witch hazel gel OL PHARMA TECH, LLC Drs PHARMACY

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.

ACTIVE INGREDIENT

- 1. Phenylephrine HCI, 0.25%
- 2. Witch Hazel, 50.0%

PURPOSE

- Vasoconstrictor
- Astringent

USES

- helps relieve the local itching and discomfort associated with hemorrhoids
- temporary relief of irritation and burning
- temporarily shrinks hemorrhoidal tissue
- aids in protecting irritated anorectal areas

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

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 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

STOP USING AND ASK YOUR DOCTOR IF

- bleeding occurs
- condition worsens or does not improve within 7 days

IF PREGNENT OR BREAST-FEEDING

ask a health professional before use.

KEEP OUT OF REACH OF CHILDREN

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

DIRECTIONS

- adults: when practical, cleanse the affected area by patting or blotting with an appropriate cleansing wipe. Gently dry by patting or blotting with a tissue or a soft cloth before applying gel.
- when first opening the tube, puncture foil seal with top end of cap
- 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: ask a doctor

OTHER INFORMATION

store at 20-25°C (68-77°F)

INACTIVE INGREDIENTS

edetate disodium, hydroxyethyl cellulose, methylparaben, propylene glycol, propylparaben, purified water, sodium citrate, sodium metabisulphite

QUESTIONS

www.drspharmacyusa.com



Tube Ø22 x 134 length 143x32x26mm



DRS. PHARMACY HEMORRHOIDAL COOLING

phenylephrine hcl, witch hazel gel

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:80489-959
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII: 1W5297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	25 mg in 1 g	
WITCH HAZEL (UNII: 101I4J0U34) (WTCH HAZEL - UNII:101I4J0U34)	WTCH HAZEL	500 mg in 1 g	

Inactive Ingredients		
Ingredient Name	Strength	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)		
SODIUM CITRATE, UNSPECIFIED FORM (UNII: 1Q73Q2JULR)		
METHYLPARABEN (UNII: A2I8C7HI9T)		
EDETATE DISODIUM (UNII: 7FLD91C86K)		
PROPYLPARABEN (UNII: Z8IX2SC1OH)		
SODIUM METABISULFITE (UNII: 4VON5FNS3C)		
HYDROXYETHYL CELLULOSE (100 MPA.S AT 2%) (UNII: R33S7TK2EP)		

P	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:80489-959- 01	1 in 1 CARTON	11/01/2021	
1		20 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	part346	11/01/2021	

Labeler - OL PHARMA TECH, LLC Drs PHARMACY (021170377)

Registrant - OL PHARMA TECH, LLC Drs PHARMACY (021170377)

Establishment				
Name	Address	ID/FEI	Business Operations	
OL PHARMA TECH, LLC Drs PHARMACY		021170377	manufacture(80489-959)	

Revised: 10/2023 OL PHARMA TECH, LLC Drs PHARMACY