OLP HEMORRHOIDAL COOLING- phenylephrine hcl, witch hazel gel
OHIO LAB PHARMA

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

Phenylephrine HCI, 0.25%

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)

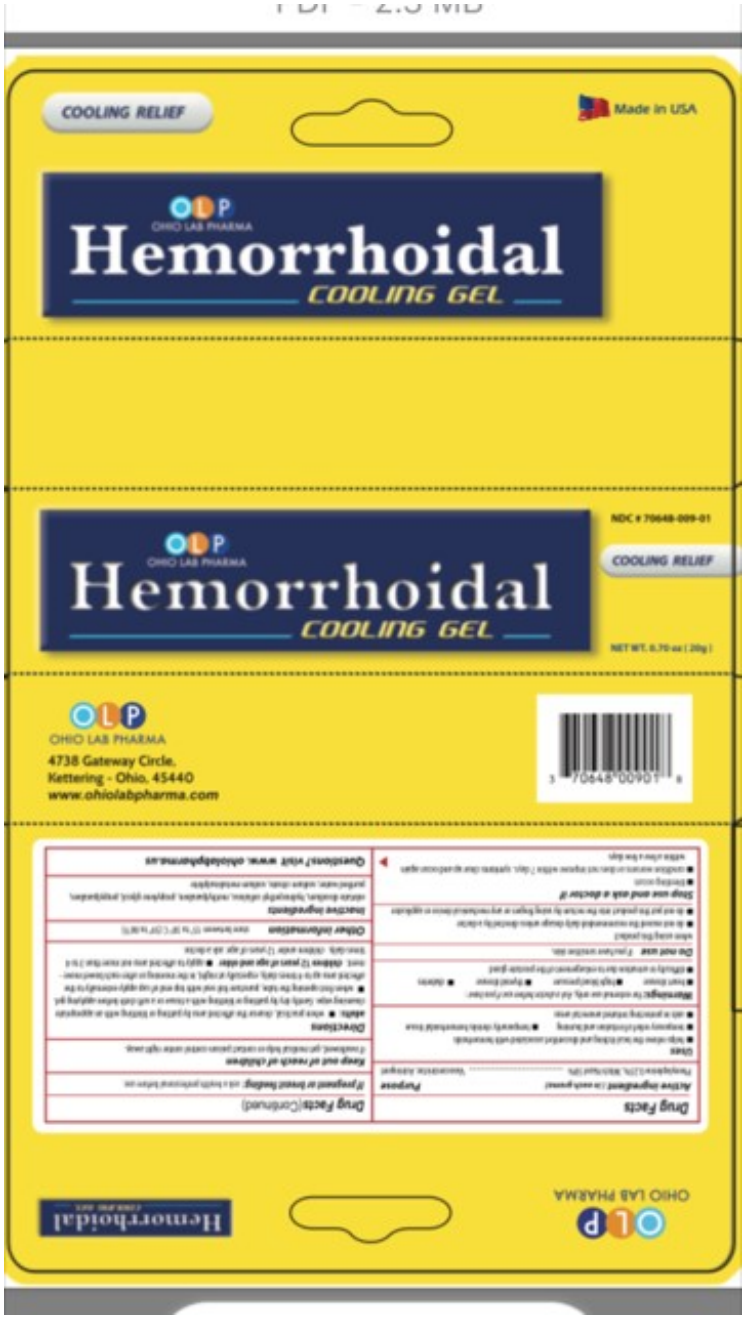
INACTIVE INGREDIENTS

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

QUESTIONS

ohiolabpharma.us

PACKAGE LABEL



COOLING RELIEF
OLP HEMORRHOIDAL COOLING GEL

OLP HEMORRHOIDAL COOLING

phenylephrine hcl, witch hazel gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:70648-009
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	25 mg in 1 g

WITCH HAZEL (UNII: 101I4J0U34) (WITCH HAZEL - UNII:101I4J0U34)	WITCH 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)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:70648-009-01	1 in 1 CARTON	02/01/2017	
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	02/01/2017	

Labeler - OHIO LAB PHARMA (080215854)

Registrant - OHIO LAB PHARMA (080215854)

Establishment

Name	Address	ID/FEI	Business Operations
OHIO LAB PHARMA		080215854	manufacture(70648-009)

Revised: 11/2018 OHIO LAB PHARMA