HEMORRHOIDAL- glycerin, phenylephrine hcl, pramoxine hcl, white petrolatum cream
Publix Super Markets Inc

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.

Publix Super Markets, Inc. Hemorrhoidal Cream Drug Facts

Active ingredients

Glycerin 14.4%

Phenylephrine HCl 0.25%

Pramoxine HCl 1%

White petrolatum 15%

Purpose

Protectant

Vasoconstrictor

Local anesthetic

Uses

- for 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 relief of anorectal discomforts
- temporarily protects the inflamed, irritated anorectal surface to help make bowel movements less painful

Warnings

For external use only

Ask a doctor before use if you have

- heart disease
- high blood pressure
- thyroid disease
- diabetes
- trouble urinating due to an enlarged 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 into the rectum by using fingers or any mechanical device or applicator

Stop use and ask a doctor if

- bleeding occurs
- condition worsens or does not improve within 7 days
- an allergic reaction develops
- the symptom being treated does not subside or if redness, irritation, swelling, pain, or other symptoms develop or increase

If pregnant 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. (1-800-222-1222)

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 cream.
- when first opening the tube, puncture foil seal with top end of cap
- apply externally or in the lower portion of the anal canal only
- apply externally to the affected area up to 4 times daily, especially at night, in the morning or after each bowel movement
- for application in the lower anal canal: remove cover from dispensing cap. Attach dispensing cap to tube. Lubricate dispensing cap well, then gently insert dispensing cap partway into the anus.
- thoroughly cleanse dispensing cap after each use and replace cover
- children under 12 years of age: ask a doctor

Other information

- store at 68°-77°F (20°-25°C)

Inactive ingredients

aloe barbadensis leaf extract, butylated hydroxyanisole, carboxymethylcellulose sodium, cetyl alcohol, citric acid, edetate disodium, glyceryl monostearate, laureth-23, methylparaben, mineral oil, panthenol, propyl gallate, propylparaben, purified water, sodium benzoate, steareth-2, steareth-20, stearyl alcohol, vitamin E, xanthan gum

Principal Display Panel

MAXIMUM STRENGTH PAIN RELIEF

hemorrhoidal cream

SMOOTH CREAM FORMULA WITH ALOE

Rapid soothing pain relief from painful burning, itching, and discomfort

Shrinks swollen hemorrhoidal tissue

Protects irritated tissue

Relieves external discomfort

Compare to the Active Ingredients in Preparation H® Cream

NET WT 1.8 OZ (51 g)

NDC 56062-944-24

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PAIN RELIEF

hemorrhoidal cream

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*This product is not manufactured or distributed by Pfizer, Marketer of Preparation H® Cream.

DO NOT USE IF TUBE SEAL UNDER CAP IS BROKEN OR MISSING

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HEMORRHOIDAL

glycerin, phenylephrine hcl, pramoxine hcl, white petrolatum cream

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:56062-944
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
GLYCERIN (UNII: PDC6A3C0OX) (GLYCERIN - UNII:PDC6A3C0OX)	GLYCERIN	14.4 g in 100 g
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	0.25 g in 100 g
PRAMOXINE HYDROCHLORIDE (UNII: 88AYB867L5) (PRAMOXINE - UNII:068X84E056)	PRAMOXINE HYDROCHLORIDE	1 g in 100 g
PETROLATUM (UNII: 4T6H12BN9U) (PETROLATUM - UNII:4T6H12BN9U)	PETROLATUM	15 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
BUTYLATED HYDROXYANISOLE (UNII: REK4960K2U)	
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED FORM (UNII: K679OBS311)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
LAURETH-23 (UNII: N72LMW566G)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
MINERAL OIL (UNII: T5L8T28FGP)	
PANTHENOL (UNII: WV9CM0O67Z)	
PROPYL GALLATE (UNII: 8D4SNN7V92)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
WATER (UNII: 059QF0KO0R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
STEARETH-2 (UNII: V56DFE46J5)	
STEARETH-20 (UNII: L0Q8IK9E08)	
STEARYL ALCOHOL (UNII: 2KR89I4H1Y)	
.ALPHA.-TOCOPHEROL (UNII: H4N855PNZ1)	
XANTHAN GUM (UNII: TTV12P4NEE)	

Product Characteristics			
Color	WHITE	**Score**	
Shape		**Size**	
Flavor		**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:56062-944-24	1 in 1 CARTON	09/14/2012	
1		51 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	09/14/2012	

Labeler - Publix Super Markets Inc (006922009)

Revised: 11/2021 Publix Super Markets Inc