

**CVS HEMORRHOIDAL - pramoxine hydrochloride, glycerin, phenylephrine hydrochloride and petrolatum cream**

**CVS 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.*

-----

**drug facts**

<b>Active ingredients</b>	<b>Purpose</b>
Glycerin 14.4%.....	Protectant
Petrolatum 15.0%.....	Protectant
Phenylephrine Hydrochloride.....	Vasoconstrictor
Pramoxine Hydrochloride.....	Local anesthetic

<b>Active ingredients</b>	<b>Purpose</b>
Glycerin 14.4%.....	Protectant
Petrolatum 15.0%.....	Protectant
Phenylephrine Hydrochloride.....	Vasoconstrictor
Pramoxine Hydrochloride.....	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

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

**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

**Other information-** store at 20 degrees - 25 degrees C (68 degrees - 77 degrees F)

**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 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

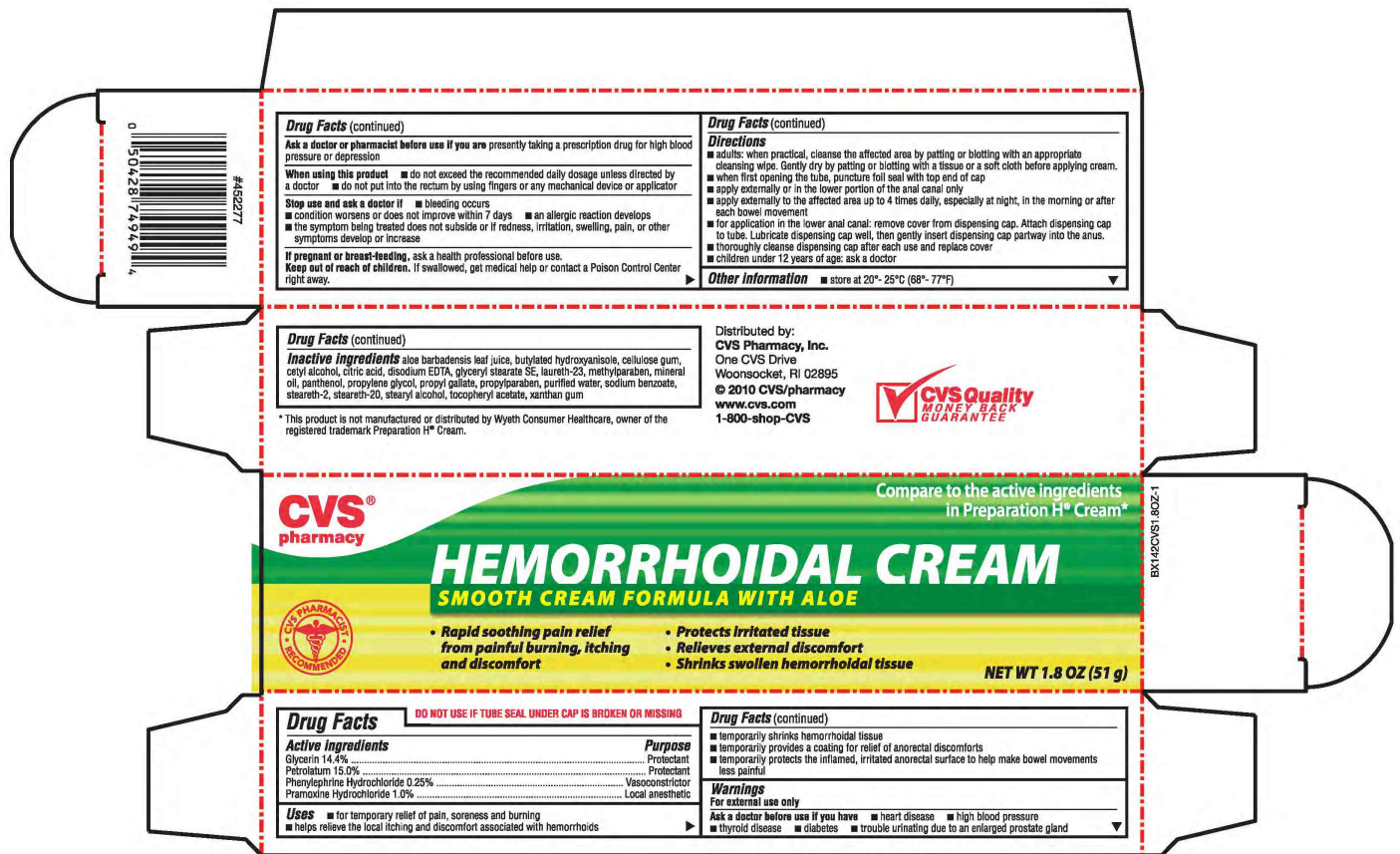
**If pregnant or breast feeding,** ask a health professional before use.

**Keep out of the 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 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 cap partway into the anus.
- thoroughly cleanse dispensing cap after each use and replace cover
- children under 12 years of age: ask a doctor

**Inactive Ingredients** aloe barbadensis leaf juice, butylated hydroxyanisole, cellulose gum, cetyl alcohol, citric acid, disodium EDTA, glyceryl stearate SE, laureth-23, methylparaben, mineral oil, penthenol, propylene glycol, propyl gallate, propylparaben, purified water, sodium benzoate, steareth-2, steareth-20, stearyl alcohol, tocopheryl acetate, xanthan gum



## CVS HEMORRHOIDAL

pramoxine hydrochloride, glycerin, phenylephrine hydrochloride and petrolatum cream

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:59779-403
Route of Administration	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
PRAMO XINE HYDRO CHLORIDE (UNII: 88AYB867L5) (PRAMO XINE - UNII:068X84E056)	PRAMO XINE HYDRO CHLORIDE	10 mg in 1 g
GLYCERIN (UNII: PDC6A3C0OX) (GLYCERIN - UNII:PDC6A3C0OX)	GLYCERIN	144 mg in 1 g
PETROLATUM (UNII: 4T6H12BN9U) (PETROLATUM - UNII:4T6H12BN9U)	PETROLATUM	150 mg in 1 g
PHENYLEPHRINE HYDRO CHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDRO CHLORIDE	2.5 mg in 1 g

### Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	

CETYL ALCOHOL (UNII: 936JST6JCN)
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311)
LAURETH-23 (UNII: N72LMW566G)
MINERAL OIL (UNII: T5L8T28FGP)
PANTHENOL (UNII: WV9CM0O67Z)
PROPYL GALLATE (UNII: 8D4SNN7V92)
STEARYL ALCOHOL (UNII: 2KR89I4HIY)
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)
SODIUM BENZOATE (UNII: OJ245FE5EU)
STEARETH-2 (UNII: V56DFE46J5)
STEARETH-20 (UNII: L0Q8IK9E08)
.ALPHA.-TOCOPHEROL ACETATE, D- (UNII: A7E6112E4N)
XANTHAN GUM (UNII: TTV12P4NEE)
ALOE VERA LEAF (UNII: ZY81Z83H0X)
BUTYLATED HYDROXYANISOLE (UNII: REK4960K2U)
EDETATE DISODIUM (UNII: 7FLD91C86K)
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)
METHYLPARABEN (UNII: A2I8C7HI9T)
PROPYLPARABEN (UNII: Z8IX2SC1OH)

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59779-403-60	1 in 1 CARTON		
1		28 g in 1 TUBE, WITH APPLICATOR		
2	NDC:59779-403-61	1 in 1 CARTON		
2		51 g in 1 TUBE, WITH APPLICATOR		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part346	12/15/2010	

**Labeler** - CVS Pharmacy (062312574)

**Registrant** - Pharma Pac, LLC (140807475)

### Establishment

Name	Address	ID/FEI	Business Operations
Pharma Pac, LLC		140807475	manufacture