

**COCOA BUTTER, PHENYLEPHRINE HYDROCHLORIDE - cocoa butter, phenylephrine hydrochloride suppository**

**CVS**

*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.*

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**drug facts**

**Active ingredients (in each suppository)**

**Purpose**

Cocoa Butter 85.5%..... Protectant  
Phenylephrine HCL 0.25%..... Vasoconstrictor

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**Uses** temporarily - Shrinks hemorrhoidal tissues - relieves itching, burning and discomfort associated with hemorrhoids

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

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**Warnings**

**For rectal use only**

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**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

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**Ask a doctor or pharmacist before use if you are** - presently taking a prescription drug for high blood pressure or depression

**Stop use and ask a doctor if**

- bleeding occurs - condition gets worse or does not improve within 7 days

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**If pregnant or breastfeeding,** ask a health professional before use

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### **Directions**

- **Adults** - if possible, clean the affected area by patting or blotting with an appropriate cleansing pad
- gently dry by patting or blotting with toilet tissue or a soft cloth before insertion of this product
- detach one suppository from strip - remove wrapper before inserting into the rectum - hold suppository with rounded end up and carefully peel film slowly and evenly down both sides to expose the suppository
- insert one suppository into rectum up to 4 times daily especially at night and morning or after each bowel movement

**Children under 12 years of age:** ask a doctor

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**Other information** - store at room temperature but not over 89 degrees F (32 degrees C)

**Inactive Ingredients** starch, shark liver oil, methylparaben, propylparaben



## COCOA BUTTER, PHENYLEPHRINE HYDROCHLORIDE

cocoa butter, phenylephrine hydrochloride suppository

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:59779-401
Route of Administration	RECTAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
COCOA BUTTER (UNII: 512OYT1CRR) (COCOA BUTTER - UNII:512OYT1CRR)	COCOA BUTTER	.855 g in 1 g
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE	.0025 g in 1 g

**Inactive Ingredients**

Ingredient Name	Strength
SHARK LIVER OIL (UNII: 4B24275HEU)	
STARCH, CORN (UNII: O8232NY3SJ)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59779-401-44	30 g in 1 BOX		
2	NDC:59779-401-45	60 g in 1 BOX		
3	NDC:59779-401-46	120 g in 1 BOX		

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part346	07/01/2011	

**Labeler** - CVS (062312574)**Registrant** - Pharma Pac, LLC (140807475)**Establishment**

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