

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

Target Corporation

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

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

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

Stop use and ask a doctor if

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

If pregnant or breastfeeding, 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** - 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

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:11673-395
Route of Administration	RECTAL		
Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
COCOA BUTTER (UNII: 512OYT1CRR) (COCOA BUTTER - UNII:512OYT1CRR)	COCOA BUTTER	850 mg in 1 g	

PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)

PHENYLEPHRINE

2.5 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
SHARK LIVER OIL (UNII: 4B24275HEU)	
STARCH, CORN (UNII: O8232NY3SJ)	
METHYL PARABEN (UNII: A2I8C7HI9T)	
PROPYL PARABEN (UNII: Z8IX2SC1OH)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:11673-395-60	12 in 1 CARTON		
1		2.5 g in 1 PACKET		

Marketing Information

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

Labeler - Target Corporation (006961700)

Registrant - Pharma Pac, LLC (140807475)

Establishment

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

Revised: 7/2011

Target Corporation