

## **HEMORRHOIDAL- hemorrhoidal suppository**

**Geritrex Corp.**

*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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### **Hemorrhoidal Suppositories**

#### **Drug Facts**

Active Ingredients Purpose

(per suppository)

Cocoa butter 85.5%.....Protectant

Phenylephrine hydrochloride 0.25%.....Vasoconstructor

#### **Uses**

temporarily shrinks hemorrhoidal tissues  
gives temporary relief to the itching, burning and  
discomfort associated with hemorrhoids  
aids in protecting irritated anorectal areas

#### **Directions**

detach one suppository from the strip. Remove the wrapper  
before inserting into the rectum  
insert one suppository into the rectum up to 4 times daily,  
especially at night, in the morning or after each bowel  
movement

Children under 12 years of age: consult a doctor

#### **WARNINGS**

For rectal use only

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

Ask a doctor before use if you have  
heart disease high blood pressure  
thyroid disease diabetes difficulty urination due to enlargement of  
the prostate gland

When using this product

do not exceed the recommended daily dosage unless  
directed by a doctor

in case of bleeding or if condition worsens or does not  
improve within 7 days, consult a doctor promptly

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

## INACTIVE INGREDIENT

methylparaben,propylparaben,shark liver oil,starch

## STORAGE

Store at room temperature or in a cool place  
but not over 80° F

## KEEP OUT OF REACH OF CHILDREN

If swallowed, get medical help or  
contact a Poison Control Center right away



# HEMORRHOIDAL

hemorrhoidal suppository

## Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:54162-045
Route of Administration	RECTAL		

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	0.25 g in 100 g
COCOA BUTTER (UNII: 512OYT1CRR) (COCOA BUTTER - UNII:512OYT1CRR)	COCOA BUTTER	85.5 g in 100 g

## Inactive Ingredients

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

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54162-045-12	2 g in 1 BOX, UNIT-DOSE	10/03/2014	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part346	02/29/2012	

**Labeler** - Geritrex Corp. (112796248)

**Registrant** - Geritrex Corp. (112796248)

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Geritrex Corp.