XYRALID HEMORRHOIDAL- hemorrhoidal suppositories suppository
Innovus Pharmaceuticals, 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.

Active ingredients

Active Ingredients Purpose

Cocoa butter 88.50%.....Protectant

Phenylephrine hydrochloride 0.26%.....Vasoconstrictor

Uses

- temporarily shrinks hemorrhoidal tissue
- temporarily relieves itching, burning, and discomfort associated with hemorrhoids
- aids in protecting irritated anorectal areas

Warnings

For rectal use only

Ask a doctor or pharmacist before use if you are

Ask a doctor or pharmacist before use if you 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 in urination due to enlargement of the prostate gland

When using this product

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

Stop use and ask a doctor if

bleeding occurs or condition worsens or does not improve within 7 days

If pregnant or breastfeeding

ask a health professional before use.

Keep out of reach of children

Keep out of 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 toilet tissue or a soft cloth.

-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

Other information

Store at 20-25ºC (68-77ºF)

Inactive ingredients

corn starch, methylparaben, propylparaben

Purpose

Protectant

Vasoconstrictor

Carton Label

XYRALID HEMORRHOIDAL

hemorrhoidal suppositories suppository

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:57483-410
Route of Administration	RECTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
COCOA BUTTER (UNII: 512OYT1CRR) (COCOA BUTTER - UNII:512OYT1CRR)	COCOA BUTTER	88.5 g in 100 g
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	0.26 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
METHYLPARABEN (UNII: A2I8C7HI9T)	0.02 g in 100 g
PROPYLPARABEN (UNII: Z8IX2SC1OH)	0.02 g in 100 g
MODIFIED CORN STARCH (1-OCTENYL SUCCINIC ANHYDRIDE) (UNII: 461P5CJN6T)	11.2 g in 100 g

Product Characteristics

Color	white	**Score**	
Shape	BULLET	**Size**	32mm
Flavor		**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:57483-410-13	4 in 1 CARTON	03/25/2018	
1	NDC:57483-410-12	24 g in 1 BLISTER PACK; 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	03/25/2018	

Labeler - Innovus Pharmaceuticals, Inc. (962507187)

Establishment

Name	Address	ID/FEI	Business Operations
Unipack, Inc.		009248480	manufacture(57483-410)

Revised: 5/2018 Innovus Pharmaceuticals, Inc.