REVIVOL-XR- phenylephrine hydrochloride suppository Unipack LLC

ReVIVOL-XR Hemorrhoid Suppositories

Active Ingredients

Phenylephrine HCI 0.25%

Purposes

Protectant

Vasoconstrictor

Uses

- helps relieve the local itching and discomfort associated with hemorrhoids
- temporarily relieves burning and 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

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

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
- children under 12 years of age: Ask a doctor

Stop use and ask a doctor if

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

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. (1-800-

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 a soft cloth before insertion of this product.
- Detach one suppository from the strip; remove the foil wrapper before inserting into the rectum as follows:
 - See full usage instructions with illustrations in the enclosed insert; carefully separate foil tabs by inserting tip of fingernail at end marked "peel down".
 - Slowly and evenly peel apart (do not tear) foil by pulling tabs down both sides, to expose the suppository. Remove the exposed suppository from the wrapper.
 - Insert one suppository into the rectum up to 4 times daily, especially at night, in the morning or after each bowel movement.

Other information

store at 15°C-30°C (59°F-86°F)

Inactive ingredients

Aloe Vera Extract and Hydrogenated Palm Kernel Oil

NDC 43749-432-01

ReVIVOL-XR®

HEMORRHOIDAL SUPPOSITORIES

Reduces Internal Swelling, Soothes and Protects

- Prompt Soothing Relief from Painful Burning, Itching and Discomfort
- Shrinks Swollen Hemorrhoidal Tissue
- Protects Irritated Tissue
- Also for Nighttime Relief

24 SUPPOSITORIES



REVIVOL-XR

phenylephrine hydrochloride suppository

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:43749-432
Route of Administration	RECTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII: 1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	6.25 mg

Inactive Ingredients		
Ingredient Name	Strength	
HYDROGENATED PALM KERNEL OIL (UNII: FM8D1RE2VP)		
ALOE VERA LEAF (UNII: ZY81Z83H0X)		

Product Characteristics			
Color	yellow (Light yellow)	Score	no score
Shape	BULLET (Bullet shaped suppository)	Size	150mm
Flavor		Imprint Code	
Contains			

P	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:43749-432- 01	24 in 1 CARTON	04/01/2025	
1		1 in 1 BLISTER PACK; Type 0: Not a Combination Product		

Marketing Information			
Marketing Category			Marketing End Date
OTC Monograph Drug	M015	04/01/2025	

Labeler - Unipack LLC (009248480)

Establishment				
Name	Address	ID/FEI	Business Operations	
Unipack LLC		009248480	manufacture(43749-432)	

Revised: 4/2025 Unipack LLC