BLISS GVS HEMORRHOIDAL- phenylephrine hcl suppository Bliss GVS Pharma Limited

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.

BLISS GVS HEMORRHOIDAL - Phenylephrine Hcl Suppository

Drug Facts

Active ingredient (in each suppository)

Phenylephrine HCI 0.25%

Purpose

Vasoconstrictor

Uses

- helps relieve the local itching and discomfort associated with hemorrhoids
- temporarily shrinks hemorrhoidal tissue
- temporarily reduces the swelling associated with irritation in hemorrhoids and other anorectal disorders

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

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

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.

Directions

- 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 suppository.
- detach one suppository from the strip
- separate the two tabs of the white plastic wrap
- with thumb and forefinger of each hand, grasp the tabs and peel downward, unwrapping the suppository
- insert one suppository into the rectum

adults and children 12 years and over: 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: ask a doctor

Other information

store at 20-25°C (68-77°F)

Inactive ingredient

Hard Fat

Questions or Comments?

Call 1-888-830-6075

TAMPER EVIDENT: DO NOT USE IF SEALED WRAPPER AROUND SUPPOSITORIES IS BROKEN OR MISSING HEMORRHOIDAL SUPPOSITORIES

NDC 72701-111-12

Prevents Further Irritation

Reduces Internal Hemorrhoidal Swelling Prompt Relief from Itching and Discomfort Also for Nighttime Relief

Bliss GVS

12 Suppositories

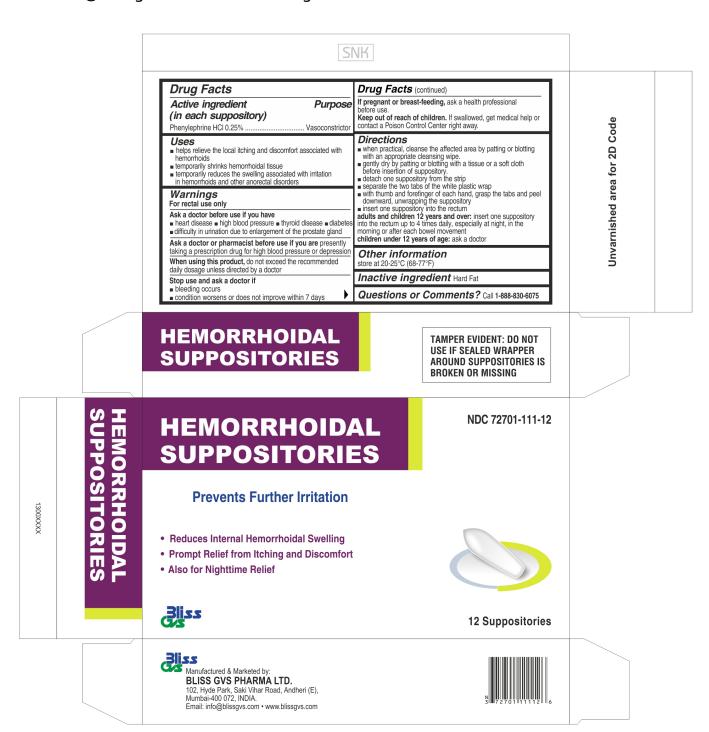
Manufactured and Marketed by:

BLISS GVS PHARMA LTD.

102, Hyde Park, Saki Vihar Road, Andheri (E),

Mumbai-400 072, INDIA

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phenylephrine hcl suppository

Product Information

HUMAN OTC DRUG NDC:72701-111 **Product Type Item Code (Source)**

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

HARD FAT (UNII: 8334LX7S21)

1

2

3

3

Packaging Marketing Start Marketing End Item Code Package Description Date Date 1 NDC:72701-111- 2 in 1 CARTON 05/25/2023 12 6 in 1 BLISTER PACK; Type 0: Not a Combination

NDC:72701-111- 4 in 1 CARTON 2 05/25/2023 6 in 1 BLISTER PACK; Type 0: Not a Combination

Product NDC:72701-111- 8 in 1 CARTON 05/25/2023

6 in 1 BLISTER PACK; Type 0: Not a Combination Product

Marketing Information

Product

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Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph final	M015	05/25/2023		

Labeler - Bliss GVS Pharma Limited (675629890)

Establishment Address Name **ID/FEI Business Operations** manufacture(72701-111) Bliss GVS Pharma Limited 675630493

Revised: 5/2023 Bliss GVS Pharma Limited