PHENAZOPYRIDINE HYDROCHLORIDE- phenazopyridine hydrochloride tablet
GPT Pharmaceuticals Private Limited

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

Drug Facts

Active ingredient (in each tablet)

Phenazopyridine Hydrochloride 99.5 mg

Purpose

Urinary tract analgesic

Uses

Relief from urinary pain, burning, urgency and frequency associated with urinary tract infections.

Warnings

Do not exceed recommended dosage.

Ask a doctor before use if you have

- kidney disease
- allergies to foods, preservatives or dyes
- had a hypersensitive reaction to Phenazopyridine Hydrochloride

Do not use

if you have Glucose-6-Phosphate Dehydrogenase (G6PD) deficiency unless approved by your physician

When using this product

- stomach upset may occur, taking this product with or after meals may reduce stomach upset
- your urine will become reddish-orange in color. This is not harmful, but care should be taken to avoid staining clothing or other items.

Stop use and ask a doctor if

- your symptoms last for more than 2 days
- you suspect you are having an adverse reaction to the medication
- long-term administration of phenazopyridine hydrochloride has induced neoplasia in rats (large intestine) and mice (liver). Although no association between

phenazopyridine hydrochloride and human neoplasia has been reported, adequate epidemiological studies along these lines have not been conducted.

If pregnant or breastfeeding,

ask a health professional before use. **A pregnancy test and consultation with a health professional if pregnancy is confirmed is recommended prior to use.**

Keep out of reach of children.

In case of an overdose, get medical help or contact a Poison Control Center call (1-800-222-1222) right away.

Directions

Adults and children 12 years and older: Take 2 tablets 3 times daily with or after meals as needed for up to two days. Take with a full glass of water. Do not use for more than 2 days (12 tablets) without consulting a doctor
Children under 12: Do not use without consulting a doctor

Other information

- This product can interfere with laboratory tests including urine, glucose (sugar), and ketones tests
- This product may stain contact lenses and other items if handled after touching tablets.
- Store in a tightly closed container

Inactive ingredients

colloidal silicone dioxide, croscarmellose sodium, hydroxypropyl methylcellulose, magnesium stearate, maize (corn) starch, microcrystalline cellulose, povidone, pregelatinized starch

PRINCIPAL DISPLAY PANEL

Phenazopyridine Hydrochloride 99.5mg Film Coated Tablets			
BATCH No.	:	BATCH SIZE	:
MFG.DATE	:	EXP.DATE	:
DRUG MFG.LICENCE No.	:	QUANTITY	: 25,000 Tablets
FEI NUMBER	: 3008311641		(Approximately 3.75 Kg)
NDC NUMBER	: 50696-003-01	DRUM No.	:

Manufactured By
GPT Pharmaceuticals Private Limited
Plot No.6/3, Road No. 11, IDA, Nacharam, Hyderabad-500076, India.
Tel: +91-40-27173033, E. Mail: mail@gptpharma.com

For Repacking Only

Storage Conditions: Store in a tightly closed container.

PHENAZOPYRIDINE HYDROCHLORIDE

phenazopyridine hydrochloride tablet

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:50696-003
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
PHENAZOPYRIDINE HYDROCHLORIDE (UNII: 0EWG668W17) (PHENAZOPYRIDINE - UNII:K2J09EMJ52)	PHENAZOPYRIDINE HYDROCHLORIDE	99.5 mg

Inactive Ingredients

Ingredient Name	Strength
MAGNESIUM STEARATE (UNII: 70097M6I30)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
STARCH, CORN (UNII: O8232NY3SJ)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	

Product Characteristics

Color	brown	**Score**	no score
Shape	ROUND	**Size**	7mm
Flavor		**Imprint Code**	WM7

Contains	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50696-003-01	25000 in 1 DRUM; Type 0: Not a Combination Product	05/01/2026	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		04/01/2026	

Labeler - GPT Pharmaceuticals Private Limited (650484871)

Registrant - GPT Pharmaceuticals Private Limited (650484871)

Revised: 5/2026 GPT Pharmaceuticals Private Limited