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# Phazorid

(Phenazopyridine HCl)

Tablet

فیزورِڈ

**COMPOSITION:**
Each film coated tablet contains:
Phenazopyridine Hydrochloride ..... 100 mg.

**Product Specs.:** USP

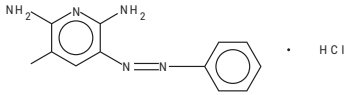
**Serious Warnings and Precautions**

Phenazopyridine produces an orange to red colour in the urine and feces and may cause staining. Phenazopyridine may cause discoloration of body fluids and staining of contact lenses has been reported. A yellowish colour of the skin sclerae may indicate accumulation of phenazopyridine resulting from impaired renal function and necessitates discontinuance of the drug. It should be noted that a decline in renal function is common in elderly patients. Phenazopyridine may mask pathological conditions and interfere with laboratory test values using colorimetric, spectrophotometric or fluorometric analysis methods.

Cautious use in patients with G-6-PD deficiency is advised since these patients are susceptible to oxidative hemolysis and may have greater potential to develop hemolytic anemia.

**DESCRIPTION:**
Phenazopyridine Hydrochloride exerts a topical analgesic effect on the mucosa of the lower urinary tract. This action helps to relieve pain, burning, urgency and frequency. The precise mechanism of action is not known. Phenazopyridine HCl is rapidly excreted by the kidneys, with as much as 65% of an oral dose being excreted unchanged in the urine.

**Structural Formula:**




**CLINICAL PHARMACOLOGY:**
**Mechanism of Action:**
Phenazopyridine is excreted in the urine where it exerts a topical analgesic effect on the mucosa of the lower urinary tract. This action helps to relieve pain, burning, urgency and frequency. The precise mechanism of action is unknown.
**Pharmacokinetics:**
The pharmacokinetic properties of phenazopyridine have not been fully elucidated. Phenazopyridine and its metabolites are rapidly excreted by the kidneys. In a small number of healthy subjects, 90% of a 600 mg/day oral dose of phenazopyridine was eliminated in the urine in 24 hours, 41% as unchanged drug and 49% as metabolites.

**INDICATIONS AND USAGE:**
**Adults (≥ 18 years old):** PHENAZOPYRIDINE HYDROCHLORIDE (Phenazopyridine Hydrochloride) is indicated for the symptomatic relief of pain, burning, urgency, frequency, and other discomforts resulting from irritation of the mucosa of the lower urinary tract caused by infection, trauma, surgery, endoscopic procedures, or the passage of sounds or catheters. Phenazopyridine is compatible with antimicrobial therapy and can help relieve pain and discomfort during the interval before an antimicrobial therapy controls the infection. Treatment with phenazopyridine should not exceed 2 days because of potential organ damage. (See Warnings and Precautions)
**Geriatrics (>65 years old):** No data are available
**Paediatrics(< 18 years old):** No data are available

**DOSAGE AND ADMINISTRATION:**
Adults: 200 mg 3 times daily after meals.
When used concomitantly with an antibacterial agent for the treatment of a urinary tract infection, the administration of phenazopyridine should not exceed 2 days. If symptoms persist, the patient should be re-evaluated.
Missed Dose: If a dose is missed, patients should take it as soon as they remember. If it is near the time of the next dose, patients should skip the missed dose and resume their usual dosing schedule. Patients should not double the dose to catch up.
Administration is by the oral route, preferably after meal.

**CONTRAINDICATIONS:**
***PHENAZOPYRIDINE HYDROCHLORIDE is contraindicated in:***
- patients who are hypersensitive to the drug or its ingredients.
- patients with renal insufficiency or any liver disease.

**ADVERSE REACTIONS:**
**Gastrointestinal:** nausea, vomiting and diarrhea.
**Nervous System:** headache, aseptic meningitis.
**Integumentary:** rash, pruritus, discoloration, jaundice,.
**Renal:** renal toxicity usually associated with overdose, renal calculi.

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**Hematologic:** methemoglobinemia, haemolytic anaemia, potential haemolytic agent in G-6-PD deficiency, sulfhemoglobinemia, neutropenia, leukopenia, pancytopenia.
**Body as a Whole:** anaphylactoid-like reaction and hypersensitivity hepatitis.
**Special Senses:** visual disturbances, eye irritation, ear pain, reversible loss of color vision.
**Other:** hepatic toxicity usually associated with overdose, discoloration of body fluids.
**USE IN SPECIFIC POPULATIONS:**
***Pregnancy.*** Reproductive studies with phenazopyridine (in combination with sulfacytine) in rats given up to 110 mg/kg/day and in rabbits given up to 39 mg/kg/day during organogenesis revealed no evidence of harm to offspring. One very limited prospective study in humans demonstrated that phenazopyridine traverses the placenta into the fetal compartment. There are no adequate and well-controlled studies in pregnant women. Therefore, phenazopyridine should be used in pregnant women only if the benefit clearly outweighs the risk.
***Lactation:*** It is unknown if the drug is excreted in human milk. Because many drugs are excreted in human milk precaution should be exercised.
***Paediatric use:*** Safety and effectiveness in children below the age of 18 have not been established.
***Geriatric use:*** Safety and effectiveness in elderly patients above 65 have not been established.
***Renal impairment:*** Phenazopyridine is contraindicated in patients with renal insufficiency. The decline in renal function associated with advanced age should be kept in mind. There are no data available in elderly patients. Phenazopyridine produces an orange to red color in the urine.
***Hepatic/Biliary/Pancreatic:*** Phenazopyridine is contraindicated in patients with any liver disease.
***Carcinogenesis and Mutagenesis:*** Long-term administration of phenazopyridine has been associated with tumors of the large intestine in rats and of the liver in mice. Available epidemiological data are insufficient to evaluate the carcinogenicity of phenazopyridine in humans. In vitro studies indicate that phenazopyridine in the presence of metabolic activation is mutagenic in bacteria and mutagenic and clastogenic in mammalian cells.
***Striated muscles:*** Treatment with phenazopyridine should not exceed 2 days. 2,3,6-triaminopyridine, a metabolite of phenazopyridine, caused extensive injury to the skeletal muscle and, to a lesser extend, the heart muscle in rats in a toxicology study. Caution is advised when giving phenazopyridine to patients with a heart condition or to patients with any neuromuscular condition.
***Hematologic:*** Patients with G-6-PD deficiency are susceptible to oxidative hemolysis and may have greater potential to develop hemolytic anemia (See Serious Warnings and Precautions). Phenazopyridine should not be used in patients with G-6-PD Mediterranean as hemolysis may occur at normal doses in these patients.
***Infection:*** The use of phenazopyridine for relief of symptoms should not delay definitive diagnosis and treatment of causative conditions. The drug should be used for symptomatic relief of pain and not as a substitute for specific surgery or antimicrobial therapy.
***Ophthalmologic:*** A yellowish color of sclerae (white of the eye) may indicate accumulation of phenazopyridine resulting from impaired renal function or overdose or taking for more than two days, and necessitates discontinuance of the drug. (See Serious Warnings and Precautions).
***Skin:*** A yellowish color of the skin may indicate accumulation of phenazopyridine resulting from impaired renal function or overdose or taking for more than two days, and necessitates discontinuance of the drug. (See Serious Warnings and Precautions).

**OVERDOSAGE:**
Exceeding the recommended dose in patients with normal renal function or administering the recommended dose to patients with reduced renal function (common in elderly patients) may lead to increased serum levels and toxic reactions. Methemoglobinemia generally follows a massive, acute overdose. Oxidative Heinz body hemolytic anemia also may occur, and "bite cells" (degmacytes) may be present in a chronic overdosage situation. Red blood cell G-6-PD deficiency may predispose to hemolysis; however, hemolysis may occur at normal doses in patients with G-6-PD Mediterranean. Renal toxicity and occasional failure and hepatic impairment may also occur.
**Treatment:** Treatment is symptomatic and supportive. Methylene blue, 1 to 2 mg/kg/dose given i.v. as a 1% solution as needed, should cause prompt reduction of the methemoglobinemia and disappearance of the cyanosis which is an aid in diagnosis.

**INSTRUCTIONS:**
- Store below 30°C.
- Protect from heat, sunlight & moisture.
- Keep out of the reach of children.
- To be sold on the prescription of a registered medical practitioner only.

**PRESENTATION:**
**Phazorid Tablet 100 mg** : Pack of 3 x 10 tablets.

**ہدایات:**
۳۰ درجہ سینٹی گریڈ سے کم درجہ حرارت پر رکھیں۔
گرمی، دھوپ اور نمی سے بچائیں۔
بچوں کی پہنچ سے دور رکھیں۔
صرف مستند ڈاکٹر کے نسخہ پر فروخت کریں۔

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