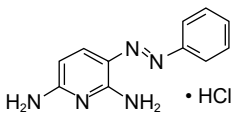
Urilef™

[Phenazopyridine HCl]

یوریلیف

Tablets 100mg

DESCRIPTION
Urilef contains Phenazopyridine HCl which is an azo dye that exerts an analgesic effect. The chemical name is 2, 6-pyridinediamine, 3-(phenylazo)-, monohydrochloride. Its molecular formula is $C_{11}H_{11}N_5$ • HCl and the structural formula is:



Phenazopyridine HCl

QUALITATIVE AND QUANTITATIVE COMPOSITION
Urilef (Phenazopyridine HCl) is available for oral administration as:

Urilef Tablets 100mg
Each film-coated tablet contains:
Phenazopyridine HCl USP…100mg

CLINICAL PHARMACOLOGY
Mechanism of Action
Phenazopyridine HCl is excreted in the urine where it exerts a topical analgesic effect on the mucosa of the urinary tract. This action helps to relieve pain, burning, urgency and frequency. The precise mechanism of action is unknown.

Pharmacokinetics
Phenazopyridine HCl is absorbed from the gastrointestinal tract. It is excreted mainly in the urine; up to 65% may be excreted as unchanged phenazopyridine HCl and 18% as paracetamol.

THERAPEUTIC INDICATIONS
Urilef (Phenazopyridine HCl) is indicated for the symptomatic relief of pain and irritability in conditions such as cystitis, prostatitis and urethritis; 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 HCl is compatible with antimicrobial therapy and can help relieve pain and discomfort during the interval before antimicrobial therapy controls the infection.

Treatment of a urinary tract infection with Phenazopyridine HCl should not exceed 2 days.

DOSAGE & ADMINISTRATION
Recommended Dose and Dosage Adjustment

Adults: 200mg 3 times daily after meals.

Children: 12mg/kg/day in 3 divided doses for 2 days.

When used concomitantly with an antibacterial agent for the treatment of a urinary tract infection, the administration of Urilef (Phenazopyridine HCl) should not exceed 2 days. If symptoms persist, the patient should be re-evaluated.

Missed Dose
If a dose is missed, patient should take it as soon as they remember. If it is near the time of the next dose, skip the missed dose and resume your usual dosing schedule. Do not double the dose to catch up.

ADVERSE REACTIONS
Nausea, vomiting, diarrhea, headache, aseptic meningitis, rash, pruritus, discoloration, jaundice, renal toxicity usually associated with overdose, renal calculi, methemoglobinemia, hemolytic anemia, acute renal failure, potential hemolytic agent in G-6-PD deficiency, sulfhemoglobinemia, anaphylactoid-like reaction, hypersensitivity, hepatitis, visual disturbances, eye irritation, ear pain, reversible loss of colour vision, hepatic toxicity usually associated with overdose, discoloration of body fluids, crystal deposits of phenazopyridine have formed in the urinary tract and aseptic meningitis, with distinct episodes of fever and confusion.

CONTRAINDICATIONS
Phenazopyridine HCl is contraindicated;
- In patients with known hypersensitivity to Phenazopyridine HCl or to any excipient of the product.
- In patients with renal insufficiency (including glomerulonephritis, uremia, pyelonephritis during pregnancy or impaired renal function).
- In patients with severe liver disease.

PRECAUTIONS
- Phenazopyridine HCl produces an orange to red colour in the urine and feces and may cause staining. Phenazopyridine HCl may cause discoloration of body fluids and staining of contact lenses has been reported. A yellowish colour of the skin or sclerae may indicate accumulation of Phenazopyridine HCl 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.
- 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.
- *Laboratory Test Interactions;* Phenazopyridine HCl may mask pathological conditions and interfere with laboratory test values using colorimetric, spectrophotometric or fluorometric analysis methods. Phenazopyridine HCl may interfere with the phenolsulfonphthalein (PSP) excretion test of kidney function; butanol may be used to extract phenazopyridine from the final alkaline urine dilution to give accurate results. Phenazopyridine HCl may interfere with urinary glucose tests. Phenazopyridine HCl may interfere with urinary ketone tests using sodium nitroprusside or Gerhardt ferric chloride by producing interfering colors. Phenazopyridine HCl may interfere with urinary urobilinogen determinations because of colour interference with Ehrlich's reagent. Phenazopyridine HCl may produce falsely elevated readings in the spectrophotofluorimetric screening tests and assays for porphyrins.
- The use of Phenazopyridine HCl 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.
- Avoid prolong use in pregnancy and lactation, stop treatment if skin or sclerae discoloration occur.

Pregnancy
Phenazopyridine HCl should be used during pregnancy, only if the potential benefit to the patient outweighs the risk to the patient and fetus.

Nursing Mothers
It is unknown if the drug is excreted in human milk. Because many drugs are excreted in human milk precaution should be exercised, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.

DRUG INTERACTION
The medical literature to date suggests that no significant interactions have been reported beside the one mentioned below:

Drug	Effect	Clinical comment
Ciprofloxacin	Increase in Ciprofloxacin bioavailability	Caution is warranted

OVERDOSAGE
Exceeding the recommended dose in patients with normal renal function or administering the recommended dose to patients with impaired renal function (common in elderly patients) may lead to increased serum levels and toxic reactions.
Methemoglobinemia generally follows a massive, acute overdose. 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. 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 for overdosage should be symptomatic and supportive.

STORAGE
Do not store above 30ºC.
Protect from sunlight and moisture.
The expiration date refers to the product correctly stored at the required conditions.

HOW SUPPLIED
Urilef (Phenazopyridine HCl) Tablets 100mg are available in blister pack of 30's.

Keep out of reach of children.

To be sold on prescription of a registered medical practitioner only.

Please read the contents carefully before use.
This package insert is continually updated from time to time.

Manufactured by:

Getz pharma (PVT) LIMITED
www.getzpharma.com
29-30/27, K.I.A., Karachi, Pakistan

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