Phenazopyridine Hydrochloride: The Use and Abuse of an Old Standby for UTI

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Phenazopyridine hydrochloride (Pyridium®, Azo-Standard®, Urogesic®, Uristat®) is an azo dye which is used as a urinary tract antiseptic and analgesic. The drug was initially marketed in the United States in 1914 as treatment for urinary tract infection (UTI), and it was widely believed to have bactericidal properties until the 1930s. In the 1940s, the first antibiotics were introduced and offered more effective and curative treatment for UTI. However, phenazopyridine is still often used as brief adjuvant therapy for treatment of UTI. Additionally, the drug is used for a number of urologic problems involving dysuria. Since a non-prescription dose is available, phenazopyridine is also used for self-medication for symptoms of UTI (Medscape DrugInfo, 2004; Zelenitsky & Zhanel, 1996). There is some evidence that inappropriate use of phenazopyridine is common (Shi et al., 2003).

Indications

The FDA labeled indication for phenazopyridine is dysuria. It is approved for symptomatic relief of pain, burning, frequency, and urgency due to irritation of the urinary tract. Common causes of irritation include infection, indwelling catheter, surgery, trauma, and invasive endoscopic procedures (cystoscopy). The drug has also been used to treat interstitial cystitis, prostatitis, and urethritis. It is widely used in clinical settings; however, controversy remains regarding whether or not there is clear evidence of effectiveness for those problems (Klasco, 2004; Rovner et al., 2000; Zelenitsky & Zhanel, 1996).

Mechanism of Action

Phenazopyridine is an azo dye and urinary tract analgesic that exerts a topical analgesic effect on urinary tract mucosa, providing symptomatic relief. It is not antibacterial in nature. In fact, the exact mechanism of action of the drug is not known (Medscape, 2004; Sweetman, 2004).

Dosage/Administration

- The typical adult oral dose is 100 to 200 mg three times daily after meals.
- Dosing interval should be increased to every 8 to 16 hours for patients with mild renal insufficiency.
- Pediatric oral dose (children ages 6-12 years) is 12 mg/kg/day in three divided daily doses.
- Supplied in 95 mg (OTC), 100 mg, 200 mg tablets (may be prepared/compounded for pediatrics as 10 mg/ml suspension).
- There is no evidence that the drug has any efficacy beyond 2 to 15 days. It is indicated for use for 2 days in combination with an antibiotic for acute UTI. It may be effective for up to 15 days for use as an analgesic. (Klasco, 2004; Medscape, 2004; Sweetman, 2004).

Overdosage

Symptoms of overdose could include oliguria, skin hyperpigmentation, sclera hyperpigmentation, or increased lethary and fatigue (Medscape DrugInfo, 2004). A patient in Chile experienced acute renal failure after ingesting at least 2,000 mg of phenazopyridine. She was hospitalized for 2 weeks, but recovered fully (Vega, 2003).

Absorption/Distribution

Phenazopyridine is absorbed from the gastrointestinal tract. The drug is excreted primarily (up to 65%) in the urine and is excreted unchanged for the most part (Sweetman, 2004).

Drug Interactions

There have been no significant food or drug interactions reported with use of phenazopyridine.

Contraindications/Precaution

- Hypersensitivity to phenazopyridine.
- Renal insufficiency.
- Liver failure/hepatitis.
- Glucose-6-phosphate dehydrogenase (G6PDH) deficiency.

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What Is It?
Phenazopyridine hydrochloride (HCL) is an oral medication available in differing strengths both by prescription and over the counter. It is an urinary tract analgesic and antiseptic and is used for relief of the pain, urgency, frequency, burning, and discomfort associated with urinary tract infections. It is also sometimes effective for pain related to other causes of urinary tract irritation or inflammation including indwelling catheters, interstitial cystitis, trauma or surgery. [Common brand names include Pyridium®, Urogesic®, AzoStandard®, Uristat®.] The drug should be stored at room temperature (59-86 degrees F.) in a cool, dry location.

What It’s Not
• Phenazopyridine is NOT an antibiotic and should not be substituted for an antibiotic.
• It will not cure a urinary tract infection. The drug is used to treat symptoms only.

How and When Is It Used?
• The usual adult dose is 100 mg to 200 mg three times a day after meals.
• The over-the-counter phenazopyridine is available in 95 mg tablets, and typical dose would be two tablets.
• The drug should be taken after meals to avoid upset stomach. It should be used for no longer than 2 days when used along with an antibiotic, and the typical use alone for symptomatic relief of other types of urinary tract irritation is less than 15 days.
• Do not “double up” if a dose is missed — just take the next scheduled dose as prescribed.

Important Fact About Phenazopyridine!
This drug contains a dye that turns the urine a reddish orange color that may permanently stain clothing, underwear, toilet seats (anything it touches). There have been reports of it staining contact lenses. The urine discoloration is not harmful and will disappear when the medication is stopped.

Who Should Not Take It or Use with Caution?
• Known kidney or renal failure
• Liver disease or hepatitis
• Known allergy or previous reaction to the drug
• Pregnancy or breast-feeding (cautious use)
• Glucose-6-phosphatedehydrogenase (G6PDH) deficiency

What About Other Medications?
• There have been no significant food or drug interactions with phenazopyridine.
• Any laboratory values requiring urine testing may be altered by phenazopyridine.

What Are Possible Side Effects?
• Nausea or upset stomach
• Headache
• Dizziness
• Rash, itching, hives
• Yellowing of sclera (whites of eyes) and/or skin tone (uncommon)
• Severe allergic reaction: difficulty breathing, rapid heart rate, seizure, fever (uncommon)

Sources: Klasco (2004); Medscape DrugInfo (2004); Sweetman (2004).

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It is interesting that the mechanism of action is still unknown. There is still significant controversy regarding its appropriate use and efficacy. Phenazopyridine can be found in abundant use in urologic clinics, and patients routinely self-medicate with the OTC brands. The drug seems to present an opportunity for further research regarding its use, misuse, and efficacy.

References

- Phenazopyridine stains may be removed from fabric by soaking in a 0.25% solution of sodium dithionite.
- Cautious use in pregnancy (category B) and nursing mothers.
- Laboratory values using urine specimens may be altered by use of phenazopyridine.
- Avoid use in patients with known renal failure or hepatitis/liver failure.
- The drug is not intended for long-term use. Caution patients regarding use longer than 2 to 15 days.
- Discoloration of skin or sclera, mucous membranes may indicate overdosage and/or toxicity — drug should be stopped immediately.

Cost
A random check of local pharmacies revealed an average price for generic phenazopyridine 200 mg for 6 tablets of $10.00, while Pyridium™ was priced at an average of $17.00. AzoStandard™ was priced at $8.00 for 30 tablets (95 mg tablets).

Conclusion
Phenazopyridine has been available and in the United States since 1914 as a urinary tract analgesic.