Pyridium Plus® Tablets

Rx Only

DESCRIPTION

Each Pyridium Plus® tablet contains:
150 mg phenazopyridine hydrochloride (Pyridium®)
0.3 mg hyoscyamine hydrobromide
15 mg butabarbital

Also contains, carnauba wax powder, colloidal silicon dioxide, FD&C Blue #2 aluminum lake, FD&C Red #40 aluminum lake, hydrogenated vegetable oil, hydroxypropyl methylcellulose, hydroxypropyl cellulose, lactose monohydrate, magnesium stearate, polyethylene glycol, polysorbate 80, pregelatinized starch, and titanium dioxide

CLINICAL PHARMACOLOGY

Pyridium Plus relieves lower urinary symptoms of pain, frequency, urgency, burning and dysuria, arising from inflammation of the urothelium, the mucosal lining of the lower urinary tract.

Lower urinary tract pain can cause reflex spasm of the detrusor. Pain and spasm are often aggravated by apprehension to promote a pain-spasm-apprehension cycle. Each of the three pharmacologic components of Pyridium Plus acts against a phase of this cycle.

Phenazopyridine hydrochloride (Pyridium), excreted in the urine, is a topical analgesic for the relief of pain and discomfort.

Hyoscyamine hydrobromide, a parasympatholytic, acts to relieve detrusor muscle spasm. Butabarbital, a short-to-intermediate acting sedative, helps to allay associated anxiety and apprehension.

INDICATIONS AND USAGE

Pyridium Plus is indicated for the symptomatic relief of pain, burning, frequency, urgency and dysuria, particularly when accompanied by the detrusor muscle spasm and apprehension.

These symptoms may arise from infection, trauma, surgery, endoscopic procedures, or the passage of sounds or catheters.

Therapy with Pyridium Plus does not interfere with antibacterial therapy and can help to relieve symptoms of pain and discomfort before definitive treatment is effective. The use of Pyridium Plus for symptomatic relief should not delay definitive diagnosis and treatment. Treatment of a urinary tract infection with Pyridium Plus should not exceed 2 days because there is lack of evidence that the combined administration of phenazopyridine hydrochloride and an antibacterial provides greater benefit than

administration of the antibacterial alone after 2 days. (See **DOSAGE AND ADMINISTRATION** Section)

In the absence of infection, Pyridium Plus may be the only medication required.

CONTRAINDICATIONS
Pyridium Plus should not be used in patients who have previously exhibited hypersensitivity to any component. The use of Pyridium Plus is contraindicated in patients with renal or hepatic insufficiency, glaucoma, bladder neck obstruction, porphyria.

WARNING
Drowsiness or dizziness may occur. Patients should be instructed to use caution in driving or operating machinery.

PRECAUTIONS
General: A yellowish tinge of the skin or sclera may indicate accumulation due to impaired renal excretion of phenazopyridine (Pyridium) and the need to discontinue therapy.

The decline in renal function associated with advanced age should be kept in mind.

Information for Patients: Phenazopyridine hydrochloride produces an orange to red color in the urine and may stain fabric. Staining of contact lenses has been reported. Butabarbital may cause drowsiness or dizziness; patients should be instructed to use caution in driving or operating machinery.

Laboratory Test Interactions: Due to its properties as an azo dye, phenazopyridine hydrochloride may interfere with urinalysis based on spectrometry or color reactions.

Carcinogenesis, Mutagenesis, Impairment of Fertility: Pyridium Plus has not undergone adequate studies relating to carcinogenesis, mutagenesis, or impairment of fertility, however the component 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.

Pregnancy Category C: Animal reproduction studies have not been conducted with Pyridium Plus. It is also not known whether Pyridium Plus can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Pyridium Plus should be given to a pregnant woman only if clearly needed.

Nursing Mothers: No information is available on the appearance of the components of Pyridium Plus in human milk.

ADVERSE REACTIONS:

Headache, rash, pruritus and occasional gastrointestinal disturbance.
Methemoglobinemia, hemolytic anemia, renal and hepatic toxicity have been described for phenazopyridine, usually at overdose levels (see **OVERDOSAGE** section). An anaphylactoid-like reaction has been described.

Hyoscyamine hydrobromide is an atropinic drug that may produce adverse effects characteristic of this class of drugs. Dry mouth, drowsiness or dizziness is noted in more than one-third of patients (and may occur in half of the patients of older age groups). Other atropine-like effects such as blurred vision may occur. There may be occasional gastrointestinal disturbances.

Butabarbital is a short-to-intermediate acting barbiturate which has the potential for adverse reactions attributable to barbiturates.

OVERDOSAGE:
Pyridium Plus is a combination of three active drugs and the overdosage can be expected to show the effects related to each ingredient. Management includes the usual measures to empty the stomach by emesis or lavage, administration of a charcoal slurry, and supportive measures as needed.

Toxicity and management suggestions relating to the individual ingredients are as follows:

Phenazopyridine Hydrochloride (Pyridium): Exceeding the recommended dose in patients with good renal function or administering the usual 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 body weight intravenously, should cause prompt reduction of the methemoglobinemia and disappearance of the cyanosis which is an aid in diagnosis. Oxidative Heinz body hemolytic anemia may also occur, and "bite cells" (degmacytes) may be present in a chronic overdosage situation. Red blood cell G-6-PD deficiency may predispose to hemolysis. Renal and hepatic impairment and occasional failure, usually due to hypersensitivity, may also occur.

Hyoscyamine Hydrobromide: Overdosage of hyoscyamine, a form of atropine, will cause dilated pupils, blurred vision, rapid pulse, increased intraoccular tension, hot, dry, red skin, dry mouth, disorientation, delirium, fever, convulsions, and coma. As an antidote, physostigmine salicylate may be given IV slowly. Dilute 1 mg in 5 mL of saline and use 1 mL of this dilution in children. Repeat every five minutes as needed up to a total of 2 mg in children, or 6 mg in adults every 30 minutes.

Butabarbital: This drug may produce sedation and respiratory depression progressing to coma, depending on the amount ingested. General and supportive measures should be instituted.

DOSAGE AND ADMINISTRATION:

Adult dosage: One tablet 4 times a day (after meals and at bedtime).

When used concomitantly with an antibacterial agent for the treatment of a urinary tract infection, the administration of Pyridium Plus should not exceed 2 days.

HOW SUPPLIED:
Pyridium Plus® tablets are dark maroon, coated, imprinted WC 182 and are supplied as follows:
N 0430-0182-15 Bottles of 30 Tablets

Store at controlled room temperature 15° to 30° C (59° to 86° F)[See USP].

Manufactured by:
Actavis Totowa LLC
Totowa, NJ 07512 USA
Marketed by:
Warner Chilcott (US), Inc.
Rockaway, NJ 07866

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