Dear Patient with Medicare Insurance Coverage:

You are probably aware that when you fill prescriptions that are covered by Medicare Part D or Medicare supplemental plans, you are not permitted to use savings coupons.

Did you know that if you pay the full price for a drug therapy, including Uribel® urinary analgesic capsules, you may use a coupon?

Just ask your pharmacist to treat your Uribel® prescription as if you were a “cash paying customer” (meaning that no insurance benefit has been provided) and you can save forty dollars off the retail price!

Depending on your pharmacy, the full price for a Uribel® prescription may be over fifty dollars. For example, if your physician has prescribed 20 capsules, the total cost with no insurance coverage would be about $60. After deducting the $40 coupon, you could lower the cost to only $20 or less. And if you have refills, you can use the coupon again and again (it’s unlimited – so hold on to it!).

We encourage you to show a copy of this letter and the coupon below to your pharmacist, and he or she will help you to obtain Uribel® therapy as economically as possible.

Please see Full Prescribing Information on reverse.
Salt (1:1); Sodium biphosphate; sodium dihydrogen phosphate; acid sodium of phosphorus oxy-chloride on a mixture of phenol and salicylic acid. Phenyl powder. Its solutions are alkaline to litmus. Affected by light, it is slightly soluble in water; freely soluble in alcohol; sparingly soluble in ether.

Methylene Blue is an alkaloid of belladonna. Exists as a white crystalline powder. Its solutions are alkaline to litmus. Freely soluble in water; soluble in alcohol and in chloroform; sparingly soluble in alcohol.

Hyoscyamine Sulfate is an alkaloid of belladonna. Exists as a white crystalline powder. Its solutions are alkaline to litmus. Freely soluble in water, soluble in alcohol and in chloroform; sparingly soluble in alcohol.

Methylene Blue [619-73-4] 3-(Benzylmethyl)phenothiazin-5-um chloride; C 63.75%, H 5.67%, Cl 11.08%, N 13.14%, S 10.03%. Methylene Blue (Methylene Blue sulfate) exists as dark green crystals. It is soluble in water and in chloroform; 3% in alcohol.

Hyoscyamine Sulfate [620-61-1] [3(S)-endo]-tropanyl-(2)-tropan-3a-(N)-tropaneacetic acid 8-methyl-8-azabicyclo[3.2.1]oct-3-yl ester sulfate(2:1). Hyoscyamine Sulfate is an alkaloid of belladonna. Exists as a white crystalline powder. Its solutions are alkaline to litmus. Freely soluble in water, soluble in alcohol and in chloroform; sparingly soluble in alcohol.

Clinical Pharmacology: HYOSCYAMINE SULFATE is a strychninoid alkaloid which relaxes smooth muscles of the gastrointestinal tract and rapidly reduced to leukomethylene blue which is stabilized in some combination form in the urine. 75% is excreted unchanged.

Phenyldiphenhydramine hydrochloride is an antihistaminic drug used to relieve the symptoms of allergic conditions.

SODIUM PHOSPHATE MONOBASIC an acidifier, helps to maintain an acid pH in the gastrointestinal tract and rapidly reduced to leukomethylene blue which is stabilized in some combination form in the urine. 75% is excreted unchanged.

INDICATIONS AND USAGE: Uribel capsules for the treatment of symptoms of tentative voiding. Indicated for the relief of local symptoms, such as increased frequency, hematuria, and pain, which accompany lower urinary tract infections. Indicated for the relief of urinary tract symptoms due to benign prostatic hypertrophy.

CONTRAINdications: Hyposensitivity to any of the ingredients is possible. Risk benefits should be carefully considered when following the medical problems exist: cardiac disease (especially cardiac arrhythmias, congestive heart failure, and mitral stenosis); gastrointestinal tract obstructive disease; glaucoma; myasthenia gravis, acute urticaria may be precipitated in obstructive uropathy (such as bladder neck obstruction due to prostatic hypertrophy). WARNINGS: Do not exceed recommended dosage. If rapid pulse, dizziness or blurring of vision occurs discontinue use immediately. PRECAUTIONS: Cross sensitivity and/or related problems - patients intolerant of belladonna alkaloids or salicylates may be intolerant of this medication also. Delay in gastric emptying could complicate the management of gastric ulcers.

PREGNANCY/Reproduction (FDA Pregnancy Category C) - hyoscyamine and methenamine across the placenta. Studies concerning the effect of hyoscyamine and methenamine on pregnancy and reproduction have not been done in animals or humans. Thus it is not known whether Uribel capsules cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Uribel capsules should be used during pregnancy only if clearly needed. Breast feeding - problems in humans have not been documented; however, methenamine and traces of hyoscyamine are excreted in breast milk. Accordingly, Uribel capsules should be given to a nursing mother with caution and only if clearly needed. Prolonged use - there have been no studies to establish the safety of prolonged use in humans. No known long-term animal studies have been performed to evaluate carcinogenic potential.

ADVERSE REACTIONS: Cardiovascular: rapid heart; flushing Central Nervous System: blurred vision, dizziness, nervousness

STORAGE: Dispense in a tight, light-resistant container as defined in the USP/NF with a child resistant closure. Store at controlled room temperature 15° - 30°C (59° - 86°F). Keep in a cool, dry place. Keep container tightly closed.

WARNING: Keep this and all drugs out of reach of children. Rx Only

Uribel® capsules contain inactive ingredients: Dicalcium Phosphate, FD&C Blue #1, FD&C Red #3, Gelatin, Magnesium Stearate, Microcrystalline Cellulose, Povidone, Propylene Glycol, Shellac, Silicon Dioxide, Sodium Hydroxide, Stearic Acid, and Titanium Dioxide.

CLINICAL PHARMACOLOGY: HYOSCYAMINE SULFATE is a strychninoid which relaxes smooth muscles and thus produces an antispasmodic effect. It is well absorbed from the gastrointestinal tract and rapidly reduced to leukomethylene blue which is stabilized in some combination form in the urine. 75% is excreted unchanged. Its biotransformation is hepatic. Its protein binding is moderate. Methenamine degrades in an acidic urine environment releasing formaldehyde which provides bactericidal or bacteriostatic action. It is hydrolyzed if the urine is acidic. Within 24 hours it is almost completely absorbed by the gastrointestinal tract and rapidly reduced to leukomethylene blue which is stabilized in some combination form in the urine. 75% is excreted unchanged. Its biotransformation is hepatic. Its protein binding is moderate.

Demonstrated in the gastrointestinal tract. 70%-90% reaches the urine at which point it is hydrolyzed if the urine is acidic. Within 24 hours it is almost completely (95%) excreted in the urine as formaldehyde. Doses of these medications should be spaced 1 hour apart from doses of hyoscyamine; antimyasthenics (concurrent use with hyoscyamine may further reduce intestinal motility); ketoconazole (patients should be asked to take this combination at least 2 hours after ketoconazole); monoamine oxidase (MAO) inhibitors (concurrent use may intensify antimuscarinic side effects); opioid (narcotic analgesics may result in increased risk of severe constipation); sulfonamides (these drugs may precipitate with formaldehyde in the urine, increasing the danger of crystalluria). Patients should be advised that the urine may become blue to blue-green and the feces may be discolored as a result of the excretion of the Methylene blue.

Drug Abuse and Dependence: A dependence on the use of Uribel® capsules has not been reported and due to the nature of its ingredients, abuse of Uribel® capsules is not expected.

OVERDOSAGE: Emergent or gastric lavage. Slow intravenous administration of physostigmine in doses of 1 to 4 mg (0.5 to 1 mg in children), repeated as needed in one to two hours to reverse severe antimuscarinic symptoms. Administration of small doses of disodium to correct exciton and seizures. Artificial respiration with oxygen if needed for respiratory depression. Adequate hydration. Symptomatic treatment as necessary. If overdose is suspected, contact your local poison center or emergency room immediately. US residents can contact the US National Poison Hotline at 1-800-222-1222.

Dosage and Administration: Adults - one capsule orally 4 times per day followed by liberal fluid intake. Children - doses should be reduced by physician. Not recommended for use in children six years of age or younger.

How Supplied: Uribel® capsules are purple/purple capsules imprinted “U” and “611”. NDC 0076-0111-01, Bottle of 100 Capsules and NDC 0076-0111-92, Carton of 20 individually packaged capsules.

Storage: Dispense in a tight, light-resistant container as defined in the USP/NF with a child resistant closure. Store at controlled room temperature 15° - 30°C (59° - 86°F). Keep in a cool, dry place. Keep container tightly closed.

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