

In the treatment of genitourinary tract infections, when the need arises for antimicrobial and analgesic action consider **Urobiotic®**

Each capsule contains: Terramycin®
(oxytetracycline as the HCl), 125 mg. with glucosamine HCl;
sulfamethizole, 250 mg.; phenazopyridine HCl, 50 mg.

Product Information

Actions: Urobiotic is a product designed for use specifically in urinary tract infections.

Terramycin® (oxytetracycline) is a widely used antibiotic with clinically proved activity against gram-positive and gram-negative bacteria, rickettsiae, spirochetes, large viruses, and certain protozoa.

Sulfamethizole is a chemotherapeutic agent active against a number of important gram-positive and gram-negative bacteria.

Phenazopyridine is an orally absorbed agent which produces prompt and effective local analgesia in the urinary tract.

Indications: Urobiotic is indicated in the therapy of a number of genitourinary infections caused by susceptible organisms. These infections include the following: pyelonephritis, pyelitis, ureteritis, cystitis, prostatitis, and urethritis. Both antibacterial components are active against the most common urinary pathogens, including *Escherichia coli*, *Pseudomonas aeruginosa*, *Aerobacter aerogenes*, *Streptococcus faecalis*, *Streptococcus hemolyticus*, and *Micracoccus pyogenes*. Urobiotic is particularly useful in the treatment of infections caused by bacteria more sensitive to the combination than to either component alone. The combination is also of value in those cases with mixed infections, and in those instances where identification of the causative organism is pending laboratory isolation.

Contraindications: This drug is contraindicated in individuals who have shown hypersensitivity to any of its components.

This drug, because of the sulfonamide component, should not be used in patients with a history of sulfonamide sensitivities, in pregnant females at term, in premature infants, or in newborn infants during the first week of life.

Warnings: Reduce usual oral dosage and consider serum level determinations in patients with impaired renal function, to prevent possible liver toxicity.

Oxytetracycline, which is one of the ingredients of Urobiotic, may form a stable calcium complex in any bone-forming tissue with no serious harmful effects reported thus far in humans. Use of oxytetracycline during the last trimester of pregnancy, neonatal period and early childhood may cause discoloration of developing teeth. This effect occurs mostly during long-term use of the drug, but it has also been observed in usual short-treatment courses.

Certain hypersensitive individuals may develop a photodynamic reaction precipitated by exposure to direct sunlight which may also be produced by other tetracycline derivatives. Should such a reaction occur and in individuals with a history of such reactions, exposure to direct sunlight should be avoided and the drug should be discontinued at first evidence of reaction.

NOTE: Photoallergic reactions to Terramycin (oxytetracycline) are exceedingly rare and phototoxic reactions are not believed to occur.

Because of its sulfonamide content, this drug should be used only after critical appraisal in patients with liver damage, renal damage, urinary obstruction, or blood dyscrasias. Deaths have been reported from hypersensitivity reactions, agranulocytosis, aplastic anemia, and other blood dyscrasias associated with sulfonamide administration. When used intermittently, or for a prolonged period, blood counts and liver and kidney function tests should be performed.

Precautions: As with all antibiotic preparations, use of this drug may result in overgrowth of nonsusceptible organisms, including fungi. If superinfection occurs, the antibiotic should be discontinued and appropriate specific therapy should be instituted.

Increased intracranial pressure with bulging fontanelles has been observed occasionally in infants receiving therapeutic doses of oxytetracycline.

Although the mechanism for this phenomenon is unknown, the signs and symptoms have disappeared rapidly upon cessation of treatment with no sequelae.

This drug should be used with caution in persons having histories of significant allergies and/or asthma.

Adverse Reactions: Nausea, diarrhea, glossitis, stomatitis, proctitis, vaginitis and dermatitis, as well as reactions of an allergic nature, may occur during oxytetracycline therapy, but are rare. If adverse reactions, individual idiosyncrasy, or allergy occur, discontinue medication.

As in all sulfonamide therapy, the following reactions may occur: nausea, vomiting, diarrhea, hepatitis, pancreatitis, blood dyscrasias, neuropathy, drug fever, skin rash, injection of the conjunctiva and sclera, petechiae, purpura, hematuria and crystalluria. The dosage should be decreased or the drug withdrawn, depending upon the severity of the reaction. **Dosage:** In adults, 1-2 capsules q.i.d. is suggested. In children under 100 lbs., 1 capsule q.i.d.; in children under 60 lbs., 1 capsule t.i.d. In acute urinary tract infections, therapy should be continued for a minimum of seven days or until bacteriologic cure occurs.

To aid absorption of the drug, it should be given at least one hour before or two hours after eating. Aluminum hydroxide gel given with antibiotics has been shown to decrease their absorption and is contraindicated.

Supply: Urobiotic Capsules: bottles of 50.

More detailed professional information available on request.

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