PDR

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A few minutes spent familiarizing yourself with the contents and organization of PDR's five color-coded sections will be amply repaid in time saved locating needed drug information during the year ahead.

Pfizer—Cont.

for as long as eight hours. Bedtime instillation usually assures sleep undisturbed by the need for remedication before morning or by insomnia from central stimulation.

Children 2 to 6 years of age: It is recommended that 2 to 3 drops of Tyzine (tetrahydrozoline HCl) 0.05% Pediatric Nasal Drops be instilled in each nostril, as needed, never more often than every three hours. Relief usually lasts for several hours so that instillations are usually needed only every four to six hours.

Instillation of nose drops can be most conveniently accomplished with the patient in the lateral head-low position.

SUPPLY: Tyzine (tetrahydrozoline HCl): Nasal Solution (0.1%)—1 fl. oz. (30 cc.) and 1 pint bottles; ½ fl. oz. (15 cc.) plastic squeeze bottles.

Pediatric Nasal Drops (0.05%)—½ fl. oz. (15 cc.) bottles.

LITERATURE AVAILABLE: Yes.

UROBIOTIC®

℞

COMPOSITION: Each capsule contains: Terramycin® (oxytetracycline HCl equivalent to 125 mg. oxytetracycline); 250 mg. sulfamethizole; 50 mg. phenazopyridine HCl; with glucosamine HCl.

ACTIONS: Urobiotic is designed specifically for use in urinary tract infections. Terramycin (oxytetracycline) is active against gram-positive and gram-negative bacteria, rickettsiae, spirochetes, large viruses and certain protozoa. Terramycin (oxytetracycline HCl) is well tolerated and well absorbed after oral administration. It diffuses readily through the placenta and is present in the fetal circulation. It diffuses into the pleural fluid, and under some circumstances, into the cerebrospinal fluid. Oxytetracycline appears to be concentrated in the hepatic system and is excreted in the bile. It is excreted in the urine and in the feces, in high concentrations, in a biologically active form. Sulfamethizole is a chemotherapeutic agent active against a number of important gram-positive and gram-negative bacteria, is well absorbed, has a low degree of acetylation and is extremely soluble.

Phenazopyridine is an orally absorbed agent which produces prompt and effective local analgesia and relief of symptoms in the urinary tract. This action is confined to the urinary system and is not accompanied by generalized sedation or narcosis.

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.

Since both Terramycin (oxytetracycline HCl) and sulfamethizole provide effective levels in blood, tissue, and urine, Urobiotic provides a multiple antimicrobial approach at the site of infection. Both antibacterial components are active against the most common urinary pathogens, including *Escherichia coli, Pseudomonas aeruginosa, Aerobacter aerogenes, Streptococcus faecalis, Streptococcus hemolyticus,* and *Micrococcus 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 the causative organism is unknown 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: If renal impairment exists, even usual oral or parenteral doses may lead to excessive systemic accumulation of the drug and possible liver toxicity. Under such conditions, lower than usual doses are indicated and if therapy is prolonged, tetracycline serum level determinations may be advisable.

Oxytetracycline HCl, 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. However, use of oxytetracycline during tooth development (last trimester of pregnancy, neonatal period and early childhood) may cause discoloration of the teeth (yellow-gray-brownish). This effect occurs mostly during long-term use of the drug but it has also been observed in usual short-treatment courses.

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.

Certain hypersensitive individuals may develop a photodynamic reaction precipitated by exposure to direct sunlight during the use of this drug. This reaction is usually of the photoallergic type which may also be produced by other tetracycline derivatives. Individuals with a history of photosensitivity reactions should be instructed to avoid exposure to direct sunlight while under treatment with this or other tetracycline drugs, and treatment should be discontinued at first evidence of skin discomfort.

NOTE: Reactions of a photoallergic nature are exceedingly rare with Terramycin (oxytetracycline HCl). Phototoxic reactions are not believed to occur with Terramycin (oxytetracycline HCl).

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: Glossitis, stomatitis, proctitis, nausea, diarrhea, 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 a dose of 1-2 capsules four times daily is suggested, depending upon the severity and response of the infection. In children under 100 lbs. the suggested average dose is 1 capsule four times daily; in children under 60 lbs., 1 capsule three times daily. Therapy should be continued for a minimum of seven days or until bacteriologic cure in acute urinary tract infections.

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's.

LITERATURE AVAILABLE: Yes.

[*Shown in Product Identification Section*]

VIBRAMYCIN® Hyclate (doxycycline hyclate) CAPSULES

℞

VIBRAMYCIN® Monohydrate (doxycycline monohydrate) FOR ORAL SUSPENSION

DESCRIPTION: Vibramycin (doxycycline) is a new broad-spectrum antibiotic synthetically derived from methacycline, available as Vibramycin Monohydrate (doxycycline monohydrate) and Vibramycin Hyclate (doxycycline hydrochloride hemiethanolate hemihydrate). The chemical designation of this light-yellow crystalline powder is α-6-deoxy-5-oxytetracycline. Vibramycin (doxycycline) possesses the following useful properties not observed with previously available tetracyclines: its greater absorption from the gastrointestinal tract and its capability for once-a-day maintenance dosage.

ACTIONS: Vibramycin (doxycycline) is a broad-spectrum antibiotic and has been shown to be active *in vitro* against both gram-positive and gram-negative organisms. *In vivo* animal protection studies (PD_{50}) in mice and extensive clinical use in man have verified that Vibramycin (doxycycline) is a potent and effective antibiotic.

Vibramycin (doxycycline) differs from other tetracyclines by virtue of its greater absorption after oral administration and prolonged duration of *in vivo* antibacterial activity. Because of these factors, therapeutic effectiveness can be achieved by a once-a-day maintenance dosage. Vibramycin (doxycycline) in therapeutic doses, given once daily, will produce serum activity usually persisting for 24 to 36 hours after discontinuation of therapy.

Vibramycin (doxycycline) has been administered to 60 normal volunteers for 70 days at a dose of 200 mg./day without evidence of increased toxicity.

Studies reported to date indicate that the absorption of Vibramycin (doxycycline) is not notably influenced by the ingestion of food or milk, which do impair the absorption of certain other tetracyclines.

ANIMAL PHARMACOLOGY: As with other tetracyclines, at doses greater than those recommended for human usage, Vibramycin (doxycycline) produces discoloration of animal thyroid glands. Careful monitoring of animals and humans has disclosed no abnormalities of thyroid function studies. Also, as with other tetracyclines, at relatively high oral doses, evidence of hepatotoxicity has been noted in dogs and signs of gastrointestinal intolerance has been seen in both dogs and monkeys.

INDICATIONS: Vibramycin (doxycycline) has been found clinically effective in the treatment of a variety of infections caused by susceptible strains of gram-positive and gram-negative bacteria.

Pneumonia: Single and multilobe pneumonia and bronchopneumonia due to susceptible strains of Pneumococcus, Streptococcus, Staphylococcus, *H. influenzae,* and *Klebsiella pneumoniae.*

Other Respiratory Tract Infections: Pharyngitis, tonsillitis, otitis media, bronchitis and sinusitis caused by susceptible strains of β-hemolytic Streptococcus, Staphylococcus, Pneumococcus and *H. influenzae.*

Genitourinary Tract Infections: Pyelonephritis, cystitis, urethritis, caused by susceptible strains of the Klebsiella-Aerobacter group, *E. coli,* Enterococcus, Staphylococcus, Streptococcus, and *Neisseria gonorrhea.* Gonococcal urethritis, in the male, has been effectively treated by Vibramycin (doxycycline) at a dose of 100 mg. t.i.d. for a single day, but highest cure rates were achieved by a dose of 50 to 100 mg. b.i.d. for two to four

days. Adult females with acute gonorrheal infections may require more extended therapy.

Soft Tissue Infections: Impetigo, furunculosis, cellulitis, abscess, infected traumatic and postoperative wounds, paronychia, caused by susceptible strains of *Staphylococcus aureus* and *albus*, Streptococcus, *E. coli*, and the Klebsiella-Aerobacter group. In the treatment of soft tissue infections, indicated surgical procedures should be carried out in conjunction with Vibramycin (doxycycline) treatment.

Since Vibramycin (doxycycline) is a member of the tetracycline series of antibiotics, it may be expected to be useful in the treatment of infections which respond to other tetracyclines. These include infections caused by susceptible organisms, such as:

Ophthalmic Infections: Due to susceptible strains of Gonococci, Staphylococci, and *H. influenzae*.

Gastrointestinal Infections: Due to susceptible strains of such organisms as E. histolytica, pathogenic *E. coli*, and species of Shigella and Salmonella.

Miscellaneous: Other infections due to susceptible strains of Bacteroides, Pasteurella, Brucella (in combination with streptomycin), Psittacosis, Listeria, Rickettsia, *Mycoplasma pneumoniae* (Eaton agent, PPLO), *H. pertussis*, *B. anthracis*, *C. welchii*, *N. meningitidis*, spirochetes (Treponema), *Donovania granulomatis*, and prostatitis and trigonitis due to Proteus or Pseudomonas.

Vibramycin (doxycycline) may be useful in the treatment of *acne vulgaris* and *acne conglobata*.

CONTRAINDICATIONS: This drug is contraindicated in individuals who have shown hypersensitivity to it.

WARNINGS: If renal impairment exists, even usual doses may lead to excessive systemic accumulation of the drug and possible hepatic toxicity. Under such conditions, lower than usual doses are indicated and if treatment is prolonged, Vibramycin (doxycycline) serum level determinations may be advisable.

As with other tetracyclines, Vibramycin (doxycycline) may form a stable calcium complex in any bone-forming tissue, though *in vitro* it binds calcium less strongly than other tetracyclines.

Though not observed in clinical studies to date and until evidence to the contrary develops, it should be anticipated that, like other tetracyclines, the use of Vibramycin (doxycycline) during tooth development (last trimester of pregnancy, neonatal period, and early childhood) may cause discoloration of teeth (yellow-gray-brownish). This tetracycline effect is more commonly associated with long-term use of the drug, but has been known to occur with treatment of short duration.

Increased intracranial pressure with bulging fontanelles has been observed in infants receiving therapeutic doses of tetracyclines. Although the mechanism of this phenomenon is unknown, the signs and symptoms have disappeared rapidly upon cessation of treatment with no sequelae.

Certain hypersensitive individuals may develop a photodynamic reaction precipitated by exposure to direct sunlight during the use of this drug. This reaction may also be produced by other tetracycline derivatives and is usually of the photoallergic type. Individuals with a history of photosensitivity reactions should be instructed to avoid exposure to direct sunlight while under treatment with tetracycline drugs, and treatment should be discontinued at first evidence of skin discomfort.

PRECAUTIONS: The use of antibiotics may occasionally result in overgrowth of nonsusceptible organisms. Constant observation of the patient is essential. If a resistant infection appears, the antibiotic should be discontinued and appropriate therapy instituted.

When treating gonorrhea in which lesions of primary or secondary syphilis are suspected, proper diagnostic procedures, including darkfield examinations, should be utilized. In all cases in which concomitant syphilis is suspected, monthly serological tests should be made for at least four months.

ADVERSE REACTIONS: Nausea, vomiting, diarrhea, vaginitis, and dermatitis, as well as reactions of an allergic nature may occur but are rare. Glossitis, stomatitis, proctitis, onycholysis and discoloration of the nails may rarely occur during tetracycline therapy as with other antibiotics. If severe adverse reactions, individual idiosyncrasy, or allergy occur, discontinue medication.

As with other tetracyclines, elevation of SGOT or SGPT values, anemia, neutropenia, eosinophilia or elevated BUN have been reported, the significance of which is not known at this time.

DOSAGE: The usual dose of Vibramycin (doxycycline) is 200 mg. on the first day of treatment (administered 100 mg. every 12 hours) followed by a maintenance dose of 100 mg./day. The maintenance dose may be administered as a single dose, or as 50 mg. every 12 hours. In the management of more severe infections (particularly chronic infections of the urinary tract), 100 mg. every 12 hours is recommended. The recommended dosage schedule for children weighing 100 pounds or less is 2 mg./lb. of body weight divided into two doses on the first day of treatment, followed by 1 mg./lb. of body weight given as a single daily dose or divided into two doses, on subsequent days. For more severe infections up to 2 mg./lb. of body weight may be used. For children over 100 lbs. the usual adult dose should be used.

Therapy should be continued beyond the time that symptoms and fever have subsided. It should be noted, however, that effective antibacterial levels are usually present 24 to 36 hours following discontinuation of Vibramycin (doxycycline). When used in streptococcal infections, therapy should be continued for 10 days to prevent the development of rheumatic fever or glomerulonephritis.

Studies reported to date indicate that the absorption of Vibramycin (doxycycline), unlike certain other tetracyclines, is not markedly influenced by simultaneous ingestion of food or milk.

Simultaneous administration of aluminum hydroxide gel given with tetracycline antibiotics including Vibramycin (doxycycline) has been shown to decrease absorption.

SUPPLY: Vibramycin Hyclate (doxycycline hyclate) is available as capsules containing doxycycline hyclate equivalent to 50 mg. of doxycycline; bottles of 50. Vibramycin Monohydrate (doxycycline monohydrate) is available as a dry powder for oral suspension containing, when reconstituted, doxycycline monohydrate equivalent to 25 mg. of doxycycline/5 cc. (each teaspoonful), with a pleasant tasting, raspberry flavor; 2 oz. bottles.

LITERATURE AVAILABLE: Yes.

[*Shown in Product Identification Section*]

VISTARIL® ℞
(hydroxyzine pamoate)
CAPSULES and ORAL SUSPENSION

VISTARIL®
(hydroxyzine hydrochloride)
PARENTERAL SOLUTION

ACTIONS: Hydroxyzine is unrelated chemically to phenothiazine, reserpine, and meprobamate. Hydroxyzine has demonstrated its clinical effectiveness in the chemotherapeutic aspect of the total management of neuroses and emotional disturbances manifested by anxiety, tension, agitation, apprehension or confusion.

Hydroxyzine has been shown clinically to be a rapid-acting, true ataraxic with a wide margin of safety. It induces a calming effect in anxious, tense, psychoneurotic adults and also in anxious, hyperkinetic children without impairing mental alertness. It is not a cortical depressant, but its action may be due to a suppression of activity in certain key regions of the subcortical area of the central nervous system.

Primary skeletal muscle relaxation, antispasmodic properties (apparently medicated through interference with the mechanism that responds to spasmogenic agents such as serotonin, acetylcholine, and histamine), and antihistaminic effects have been demonstrated experimentally and the latter confirmed clinically. An antiemetic effect, both by the apomorphine and the veriloid test, has been demonstrated. Pharmacologic and clinical studies indicate that hydroxyzine in therapeutic dosage does not increase gastric secretion or acidity and in most cases provides mild antisecretory benefits.

Hydroxyzine pamoate is rapidly absorbed in the gastrointestinal tract and the effects of Vistaril (hydroxyzine pamoate) are usually noted within 15 to 30 minutes after oral administration.

INDICATIONS: The total management of anxiety, tension, and psychomotor agitation in conditions of emotional stress requires in most instances a combined approach of psychotherapy and chemotherapy. Hydroxyzine has been found to be particularly useful for this latter phase of therapy in its ability to render the disturbed patient more amenable to psychotherapy in long-term treatment of the psychoneurotic and the psychotic, although it should not be used as the sole treatment of psychosis or of clearly demonstrated cases of depression.

Hydroxyzine is also useful in alleviating the manifestations of anxiety and tension as in the preparation for dental procedures and in acute emotional problems. It has also been recommended for the management of anxiety associated with organic disturbances and as adjunctive therapy in alcoholism and allergic conditions with strong emotional overlay, such as in asthma, chronic urticaria, and pruritus.

Vistaril (hydroxyzine hydrochloride) Parenteral Solution is useful in treating the following types of patients when parenteral administration is indicated.

1. The acutely disturbed or hysterical patient.
2. The acute or chronic alcoholic with anxiety withdrawal symptoms, or delirium tremens.
3. As pre- and postoperative and pre- and postpartum adjunctive medication to permit reduction in narcotic dosage, allay anxiety and control emesis.

Vistaril (hydroxyzine hydrochloride) has also demonstrated effectiveness in controlling nausea and vomiting, excluding nausea and vomiting of pregnancy. (See CONTRAINDICATIONS).

Clinical use of hydroxyzine hydrochloride as an adjunct to the management of labor has been extensively reported in the literature without evidence of harm to the mother or neonate.

Hydroxyzine benefits the cardiac patient by its ability to allay the associated anxiety and apprehension attendant to certain types of heart disease. Hydroxyzine is not known to interfere with the action of digitalis in any way and may be used concurrently with this agent.

Its effectiveness and safety make it an outstanding drug for long-term use.

CONTRAINDICATIONS: Hydroxyzine hydrochloride parenteral solution is intended only for intramuscular or intravenous administration and should not, under any circumstances, be injected subcutaneously or intra-arterially.

Hydroxyzine is contraindicated for patients who have shown a previous hypersensitivity to it.

Hydroxyzine, when administered to the pregnant mouse, rat, and rabbit, induced fetal abnormalities in the rat at doses substantially above the human therapeutic range. Clinical data in human beings are inadequate to establish safety in early preg-

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