Tetracycline is a yellow, odorless, crystalline powder. Tetracycline is stable in air but suspected to be caused by bacteria. For testing Tetracycline hydrochloride and other antibacterial drugs, tetracycline hydrochloride have been found to be resistant to tetracycline. Streptococcus faecalis and Streptococcus pyogenes have been shown to be resistant to tetracycline, culture and susceptibility testing have demonstrated to be susceptible. Therefore, tetracyclines should not be used for streptococcal disease unless other therapy should be selected.

For testing: 

- Neisseria gonorrhoeae: ≤ 14 Resistant (R) ≥ 16
- Haemophilus influenzae: ≤ 14 Resistant (R) ≥ 16
- Staphylococcus aureus: 0.25 to 1
- Streptococcus pneumoniae: 0.5 to 1
- Neisseria meningitidis: 0.06 to 0.1
- Neisseria gonorrhoeae: ≤ 0.25

These zone diameter standards are applicable only to disk diffusion testing using 6 mm diameter disks. These interpretive standards are applicable to disk diffusion testing using Mueller-Hinton agar with 5 to 7% sheep blood.

For testing: 

- Haemophilus influenzae: ≤ 0.25
- Staphylococcus aureus: ≤ 0.5

These zone diameter standards are applicable only to disk diffusion testing using Mueller-Hinton agar with 5 to 7% sheep blood and a 30 mcg tetracycline disk.

As with standardized dilution techniques, diffusion methods require the use of laboratory control microorganisms that are used to control the technical aspects of the laboratory procedures. For the diffusion technique, the 30 mcg tetracycline disk should provide the following zone diameters in these laboratory test quality control strains:

- Escherichia coli: ≥ 20 mm
- Staphylococcus aureus: ≥ 15 mm
- Streptococcus faecalis: ≥ 10 mm

These zone diameter standards are applicable only to disk diffusion testing using tetracycline hydrochloride capsules USP other antibacterial drugs, tetracycline hydrochloride capsules USP should be used only to treat or prevent infections that are proven or strongly suspected to be caused by susceptible bacteria. Laboratory control microorganisms that are used to control the technical aspects of the laboratory procedures. For the diffusion technique, the 30 mcg tetracycline disk should provide the following zone diameters in these laboratory test quality control strains:

- Escherichia coli: ≥ 20 mm
- Staphylococcus aureus: ≥ 15 mm
- Streptococcus faecalis: ≥ 10 mm

These zone diameter standards are applicable only to disk diffusion testing using Mueller-Hinton agar with 5 to 7% sheep blood and a 30 mcg tetracycline disk.

As with standardized dilution techniques, diffusion methods require the use of laboratory control microorganisms that are used to control the technical aspects of the laboratory procedures. For the diffusion technique, the 30 mcg tetracycline disk should provide the following zone diameters in these laboratory test quality control strains:

- Escherichia coli: ≥ 20 mm
- Staphylococcus aureus: ≥ 15 mm
- Streptococcus faecalis: ≥ 10 mm

These zone diameter standards are applicable only to disk diffusion testing using Mueller-Hinton agar with 5 to 7% sheep blood and a 30 mcg tetracycline disk.

As with standardized dilution techniques, diffusion methods require the use of laboratory control microorganisms that are used to control the technical aspects of the laboratory procedures. For the diffusion technique, the 30 mcg tetracycline disk should provide the following zone diameters in these laboratory test quality control strains:

- Escherichia coli: ≥ 20 mm
- Staphylococcus aureus: ≥ 15 mm
- Streptococcus faecalis: ≥ 10 mm

These zone diameter standards are applicable only to disk diffusion testing using Mueller-Hinton agar with 5 to 7% sheep blood and a 30 mcg tetracycline disk.

As with standardized dilution techniques, diffusion methods require the use of laboratory control microorganisms that are used to control the technical aspects of the laboratory procedures. For the diffusion technique, the 30 mcg tetracycline disk should provide the following zone diameters in these laboratory test quality control strains:

- Escherichia coli: ≥ 20 mm
- Staphylococcus aureus: ≥ 15 mm
- Streptococcus faecalis: ≥ 10 mm

These zone diameter standards are applicable only to disk diffusion testing using Mueller-Hinton agar with 5 to 7% sheep blood and a 30 mcg tetracycline disk.

As with standardized dilution techniques, diffusion methods require the use of laboratory control microorganisms that are used to control the technical aspects of the laboratory procedures. For the diffusion technique, the 30 mcg tetracycline disk should provide the following zone diameters in these laboratory test quality control strains:

- Escherichia coli: ≥ 20 mm
- Staphylococcus aureus: ≥ 15 mm
- Streptococcus faecalis: ≥ 10 mm

These zone diameter standards are applicable only to disk diffusion testing using Mueller-Hinton agar with 5 to 7% sheep blood and a 30 mcg tetracycline disk.

As with standardized dilution techniques, diffusion methods require the use of laboratory control microorganisms that are used to control the technical aspects of the laboratory procedures. For the diffusion technique, the 30 mcg tetracycline disk should provide the following zone diameters in these laboratory test quality control strains:

- Escherichia coli: ≥ 20 mm
- Staphylococcus aureus: ≥ 15 mm
- Streptococcus faecalis: ≥ 10 mm

These zone diameter standards are applicable only to disk diffusion testing using Mueller-Hinton agar with 5 to 7% sheep blood and a 30 mcg tetracycline disk.

As with standardized dilution techniques, diffusion methods require the use of laboratory control microorganisms that are used to control the technical aspects of the laboratory procedures. For the diffusion technique, the 30 mcg tetracycline disk should provide the following zone diameters in these laboratory test quality control strains:

- Escherichia coli: ≥ 20 mm
- Staphylococcus aureus: ≥ 15 mm
- Streptococcus faecalis: ≥ 10 mm

These zone diameter standards are applicable only to disk diffusion testing using Mueller-Hinton agar with 5 to 7% sheep blood and a 30 mcg tetracycline disk.

As with standardized dilution techniques, diffusion methods require the use of laboratory control microorganisms that are used to control the technical aspects of the laboratory procedures. For the diffusion technique, the 30 mcg tetracycline disk should provide the following zone diameters in these laboratory test quality control strains:

- Escherichia coli: ≥ 20 mm
- Staphylococcus aureus: ≥ 15 mm
- Streptococcus faecalis: ≥ 10 mm

These zone diameter standards are applicable only to disk diffusion testing using Mueller-Hinton agar with 5 to 7% sheep blood and a 30 mcg tetracycline disk.

As with standardized dilution techniques, diffusion methods require the use of laboratory control microorganisms that are used to control the technical aspects of the laboratory procedures. For the diffusion technique, the 30 mcg tetracycline disk should provide the following zone diameters in these laboratory test quality control strains:

- Escherichia coli: ≥ 20 mm
- Staphylococcus aureus: ≥ 15 mm
- Streptococcus faecalis: ≥ 10 mm

These zone diameter standards are applicable only to disk diffusion testing using Mueller-Hinton agar with 5 to 7% sheep blood and a 30 mcg tetracycline disk.

As with standardized dilution techniques, diffusion methods require the use of laboratory control microorganisms that are used to control the technical aspects of the laboratory procedures. For the diffusion technique, the 30 mcg tetracycline disk should provide the following zone diameters in these laboratory test quality control strains:

- Escherichia coli: ≥ 20 mm
- Staphylococcus aureus: ≥ 15 mm
- Streptococcus faecalis: ≥ 10 mm

These zone diameter standards are applicable only to disk diffusion testing using Mueller-Hinton agar with 5 to 7% sheep blood and a 30 mcg tetracycline disk.

As with standardized dilution techniques, diffusion methods require the use of laboratory control microorganisms that are used to control the technical aspects of the laboratory procedures. For the diffusion technique, the 30 mcg tetracycline disk should provide the following zone diameters in these laboratory test quality control strains:

- Escherichia coli: ≥ 20 mm
- Staphylococcus aureus: ≥ 15 mm
- Streptococcus faecalis: ≥ 10 mm

These zone diameter standards are applicable only to disk diffusion testing using Mueller-Hinton agar with 5 to 7% sheep blood and a 30 mcg tetracycline disk.

As with standardized dilution techniques, diffusion methods require the use of laboratory control microorganisms that are used to control the technical aspects of the laboratory procedures. For the diffusion technique, the 30 mcg tetracycline disk should provide the following zone diameters in these laboratory test quality control strains:

- Escherichia coli: ≥ 20 mm
- Staphylococcus aureus: ≥ 15 mm
- Streptococcus faecalis: ≥ 10 mm

These zone diameter standards are applicable only to disk diffusion testing using Mueller-Hinton agar with 5 to 7% sheep blood and a 30 mcg tetracycline disk.
The antiinfective action of the tetracyclines may cause an increase in BUN. While this is not a problem in those with normal renal function, in patients with significantly impaired renal function, higher serum levels of tetracycline may lead to azotemia, hyperphosphatemia and acidosis.

PRECAUTIONS

General
As with other antibiotics, use of this drug may result in overgrowth of nonsusceptible organisms, including fungi. If superinfection occurs, the antibiotic should be discontinued and appropriate therapy should be instituted.

All infections due to Group A beta-hemolytic streptococci should be treated for at least ten days.

Bulging fontanelles in infants and benign intracranial hypertension in adults have been reported in individuals receiving tetracyclines. These conditions disappeared when the drug was discontinued.

Incision and drainage or other surgical procedures should be performed in conjunctive with antibiotic therapy, when indicated.

Prescribing tetracycline in the absence of proven or strongly suspected bacterial infection or a prophylactic indication is unlikely to provide benefit to the patient and increases the risk of the development of resistant bacteria.

Information for Patients

Patients should be counseled that antibacterial drugs including tetracycline should only be used to treat bacterial infections. They do not treat viral infections (e.g., the common cold). When tetracycline is prescribed to treat a bacterial infection, patients should be told that although it is common to feel better early in the course of therapy, the medication should be taken exactly as directed. Skipping doses or not completing the full course of therapy may (1) decrease the effectiveness of the immediate treatment and (2) increase the likelihood that bacteria will develop resistance and will not be treatable by tetracycline or other antibacterial drugs in the future.

Laboratory Tests

In general, when consistent signs of infection are suspected, dark field examinations should be done before treatment is started and the blood smear repeated monthly, for at least four months.

In long-term therapy, periodic laboratory evaluation of organ systems, including hematopoietic, renal and hepatic studies, should be performed.

Drug Interactions

Since bacteriostatic drugs may interfere with the bactericidal action of penicillin, it is advisable to avoid giving tetracycline in conjunction with penicillin or other bacteriostatic antibiotics.

Because the tetracyclines have been shown to depress plasma prothrombin activity, patients who are on anticoagulant therapy may require downward adjustment of their anticoagulant dosage.

 Concurrent use of tetracycline and methotr Yasfuran has been reported to result in fatal renal toxicity.

Absorption of tetracyclines is impaired by antacids containing aluminum, calcium or magnesium and preparations containing iron, zinc, or sodium bicarbonate.

Concurrent use of tetracycline may render oral contraceptives less effective.

Carcinogenesis, Mutagenesis, Impairment of Fertility

Long-term animal studies are currently being conducted to determine whether tetracycline hydrochloride has carcinogenic potential.

Some related antibiotics (oxytetracycline, minocycline) have shown evidence of oncogenic activity in rats. In two in vivo mammalian cell assay systems (L 51784y mouse lymphoma and Chinese hamster lung cells), there was evidence of mutagenicity at tetracycline hydrochloride concentrations of 60 and 10 mcg/mL, respectively.

Tetracycline hydrochloride had no effect on fertility when administered in the diet to male and female rats at a daily intake of 25 times the human dose.

Pregnancy

Teratogenic Effects

Pregnant women with renal disease may be more prone to develop tetracycline-associated liver failure.

Labor and Delivery

The effect of tetracyclines on labor and delivery is unknown.

Nursing Mothers

Because of the potential for serious adverse reaction in nursing infants from tetracyclines, a decision should be made whether to discontinue the drug, taking into account the importance of the drug to the mother (see WARNINGS).

Pediatric Use

See WARNINGS and DOSAGE AND ADMINISTRATION.

ADVERSE REACTIONS

Gastrointestinal: anemia, nausea, epigastric distress, vomiting, diarrhea, glossitis, black hairy tongue, dysphagia, enterocolitis, and inflammatory lesions (with monilial superinfection) occasionally seen in association with tetracycline therapy. Discontinue therapy immediately if these lesions worsen or fail to improve in 2-3 days.

Hypersensitivity reactions: urticaria, angioneurotic edema, anaphylaxis, anaphylactoid purpura, penicilliosis, exacerbation of systemic lupus erythematosus, and serum sickness-like reactions, as fever, rash, and arthralgia.

Biosis: hemolysis, anemia, thrombocytopenia, thrombocytopoenic purpura, neutropenia and eosinophilia have been reported.

Other: bulging fontanelles in infants and intracranial pressure in adults (see PRECAUTIONS, General).

When given over prolonged periods, tetracyclines have been reported to produce brown-black microscopic discoloration of thyroid glands. No abnormalities of thyroid function studies are known to occur.

OVERDOSAGE

In case of overdosage, discontinue medication, treat symptomatically and institute supportive measures. Tetracycline is not dialyzable.

DOSAGE AND ADMINISTRATION

Adults

Usual daily dose: 1 gram as 500 mg b.i.d. or 250 mg q.i.d. Higher doses such as 500 mg q.i.d. may be required for severe infections or for those infections which do not respond to the smaller doses.

Children above eight years of age

Usual daily dose: 500 mg in divided doses. Daily dosage may be divided into four equal