TROBICIN® Sterile Powder
(spectinomycin)

DESCRIPTION
TROBICIN® (Spectinomycin hydrochloride) is an aminocyclitol antibiolic produced by a species of soil micro - organisms designated as Streptomyces spectabilis. TROBICIN® (spectinomycin) is available in vial containing 2gm spectinomycin base.

INDICATIONS

TROBICIN® is indicated in the treatment of acute gonorrheal urethritis and proctitis in the male, and acute gonorrheal cervicitis and proctitis in the female, when due to susceptible strains of *N. gonorrhea*. Sexual contacts of individuals with known gonorrhea should also be treated.

TROBICIN is indicated as an alternative treatment of chancroid (caused by *H. ducreyi*).

DOSAGE AND ADMINISTRATION

The recommended dose of spectinomycin HCL in men or women is 2.0 gms in one intramuscular injection. Up to 4.0 gms of spectinomycin have been administered in difficult to treat cases and in areas where antibiotic resistance is known to occur. The clinical effectiveness of TROBICIN® should be monitored to detect evidence of development of resistance by N. gonorrhoea.

Dosage

Intramuscular injections should be made deep into the upper outer quadrant of the gluteal muscle.

Adults

Inject a single 2 gram dose (5 ml) I.M. If a 4 gram dose (10 ml) is necessary, the 10 ml injection may be divided between two gluteal injection sites.

Preparation of Drug for Intramuscular Injection

2 gram TROBICIN® Sterile Powder: Reconstitute with 3.2 ml of the accompanying diluent (Bacteriostatic Water for Injection with Benzyl Alcohol 0.9% w/v)

4 gram TROBICIN® Sterile Powder: Reconstitute with 6.2 ml of the accompanying diluent (Bacteriostatic Water for Injection with Benzyl Alcohol 0.9% w/v)

Shake vials vigorously immediately after adding diluent and before withdrawing dose. It is recommended that disposable syringes and needles be used to avoid contamination with penicillin residue, especially when treating patients known to be highly sensitive to penicillin. Use of 20 gauge needle is recommended.

Contraindications

TROBICIN® is contraindicated in patients previously found sensitive to it.

Warnings and Precautions

TROBICIN® is not indicated for the treatment of syphilis. Antibiotics used in high doses for short periods of time to treat gonorrhea may mask or delay the symptoms of incubating syphilis. Thus, all patients with gonorrhea should have a serological test for syphilis at the time of diagnosis. Patients treated with TROBICIN® should have a follow-up serological test for syphilis after three months.

Clostridium difficile associated diarrhea (CDAD) has been reported with use of nearly all antibacterial agents, including spectinomycin, and may range in severity from mild diarrhea to fatal colitis. Treatment with antibacterial agents alters the normal flora of the colon leading to overgrowth of *C difficile.*

C. difficile produces toxins A and B which contribute to the development of CDAD. Hypertoxin producing strains of *C. difficile* cause increased morbidity and mortality, as these infections can be refractory to antimicrobial therapy and may require colectomy. CDAD must be considered in all patients who present with diarrhea following antibiotic use. Careful medical history is necessary since CDAD has been reported to occur over two months after the administration of antibacterial agents.

Use in Pregnancy:
Spectinomycin was not teratogenic or embryocidal when orally or subcutaneously administered to rats at doses of 300 mg/kg/day. A teratology study was conducted in rats at doses up to 2500 mg/kg administered subcutaneously. No evidence of fetotoxicity or teratogenicity was observed. No teratogenic effects were observed when spectinomycin was administered intraperitoneally to mice or rats at dose levels of 400 or 1600 mg/kg/day, respectively. Spectinomycin was administered intramuscularly or subcutaneously to pregnant rabbits at dose levels up to 300 mg/kg/day. Embryonic and fetal development were unaffected by treatment. Since there are no controlled studies of spectinomycin in pregnant women, and because animal reproduction studies are not always predictive of human responses, spectinomycin should be used during pregnancy only if clearly needed.

Use in Nursing Mothers: It is not known if spectinomycin is excreted in human milk. However, spectinomycin is excreted in the milk of cows and ewes (Note: Spectinomycin is poorly absorbed from the gastrointestinal tract.)

Pediatric Use: Although safety and effectiveness in infants and children have not been definitely established, TROBICIN® has been reported to be effective in prepubertal children with uncomplicated gonococcal infection at a dosage of 40 mg/kg, intramuscularly, as a single dose

TROBICIN® is not effective in eradicating incubating syphilis or against concurrent infections with C trachomatis.

Adverse Reactions

The following reactions have been observed during single dose clinical trials: Soreness at the injection site, urticaria, dizziness, nausea, chills, fever, and a reduction in urine output (without renal function changes indicative of renal toxicity).

The following reactions have been observed during multiple-dose tolerance studies in healthy volunteers: A decrease in hemoglobin, hematocrit, and creatinine clearance; and an elevation of alkaline phosphatase, BUN, and SGPT.

Anaphylaxis or anaphylactoid reactions have been reported on rare occasions.

SHELF LIFE
TROBICIN® should not be used beyond its expiry date.

SPECIAL PRECAUTIONS FOR STORAGE
Store unreconstituted product at controlled room temperature 15^{o}-30^{o} C (59^{o}-86^{o} F). Store prepared suspension at controlled room temperature 15^{o}-30^{o} C (59^{o}-86^{o} F) and use within 24 hours.

How Supplied:
TROBICIN® sterile powder is available in 2gm vial