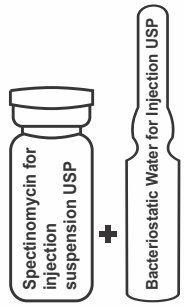
Trobicin

Sterile Powder

Spectinomycin for Injectable Suspension

2g



For I.M. use only

- *Read this leaflet carefully before you start taking this medicine.*
- *Keep this leaflet. You may need to read it again.*
- *If you have any questions, ask your doctor or pharmacist.*
- *This medicine has been prescribed for you. Do not give it to others. It may harm them, even if their symptoms are the same as yours.*
- *If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.*

COMPOSITION

Each combipack contains:

(A) Spectinomycin for Injectable Suspension USP

Each vial contains:
Spectinomycin Hydrochloride USP
equivalent to Spectinomycin 2g

(B) Bacteriostatic Water for Injection USP 3.2 ml

Each ml contains:
Benzyl Alcohol USP 9.00 mg
(As Preservative)
Water for Injection USP q.s.

DESCRIPTION

TROBBCIN Injection contains spectinomycin hydrochloride which is an aminocyclitol antibiotic produced by a species of soil microorganism designated as Streptomyces spectabilis. Sterile spectinomycin hydrochloride is the pentahydrated dihydrochloride salt of spectinomycin.

INDICATIONS AND USAGE

TROBBCIN Injection 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 Neisseria gonorrhoeae. Men and women with known recent exposure to gonorrhea should be treated as those known to have gonorrhea. To reduce the development of drug-resistant bacteria and maintain the effectiveness of TROBBCIN Injection and other antibacterial drugs, TROBBCIN Injection should be used only to treat or prevent infections that are proven or strongly suspected to be caused by susceptible bacteria. When culture and susceptibility information are available, they should be considered in selecting or modifying antibacterial therapy. In the absence of such data, local epidemiology and susceptibility patterns may contribute to the empiric selection of therapy.

DOSAGE AND ADMINISTRATION

Preparation of Drug for Intramuscular Injection

TROBBCIN 2 gram Injection reconstitute with 3.2 ml of Bacteriostatic Water for Injection USP. Shake vials vigorously immediately after adding Bacteriostatic Water for Injection and before withdrawing dose. It is recommended that disposable syringes and needles be used. A 20-gauge needle is recommended. Dosage Intramuscular injections should be made deep into the upper outer quadrant of the gluteal muscle.

Adults (Men and Women): Inject 5 ml intramuscularly for a 2 gram dose. This is also the recommended dose for patients being treated after failure of previous antibiotic therapy. In geographic areas where antibiotic resistance is known to be prevalent, initial treatment with 4 grams (10 ml) intramuscularly is preferred. The 10 ml injection may be divided between two gluteal injection sites.

OVERDOSAGE

Information on overdosage in humans is not available. Hemodialysis has been reported to aid in the removal of intravenously administered spectinomycin from the body.

CONTRAINDICATIONS

The use of TROBBCIN Injection is contraindicated in patients previously found hypersensitive to it.

WARNINGS

Spectinomycin hydrochloride is not effective in 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. Since the treatment of syphilis demands prolonged therapy with any effective antibiotic, patients being treated for gonorrhea should be closely observed clinically. All patients with gonorrhea should have a serologic test for syphilis at the time of diagnosis. Patients treated with spectinomycin hydrochloride should have a follow-up serologic test for syphilis after three months.

PRECAUTIONS

The usual precautions should be observed with atopic individuals. The clinical effectiveness of TROBBCIN Injection should be monitored to detect evidence of development of resistance by Neisseria gonorrhoeae. Prescribing TROBBCIN Injection in the absence of a 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 drug-resistant bacteria.

Information for Patients

Patients should be counseled that antibacterial drugs including TROBBCIN Injection should only be used to treat bacterial infections. They do not treat viral infections (e.g., the common cold). When TROBBCIN Injection 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 TROBBCIN Injection or other antibacterial drugs in the future.

Carcinogenesis, Mutagenesis, Impairment of Fertility

Genotoxicity of spectinomycin hydrochloride was evaluated in six assay test systems including two Ames tests, two micronucleus tests in mice, unscheduled DNA synthesis in rat primary hepatocytes, and a chromosomal aberration test in Chinese hamster ovary cells. Spectinomycin was not shown to be mutagenic or genotoxic in these tests. No adverse effects on fertility or general reproductive performance were observed when spectinomycin was administered subcutaneously to rats at dose levels up to 300 mg/kg (equivalent to the recommended maximum human dose based on mg/m2). A threegeneration reproduction study in rats administered spectinomycin hydrochloride orally at dose levels up to 400 mg/kg (equivalent to the recommended maximum human dose based on mg/m2) produced no evidence of drug-induced toxicity during growth, gestation, or lactation periods of any parental generation. Pregnancy rates of the 400 mg/kg/day groups were consistently lower than those of the control groups. A histopathological examination of the testes and ovaries of the third generation animals was normal.

Pregnancy:

Teratogenic Effects. Pregnancy Category B

Spectinomycin was not teratogenic or embryocidal when orally or subcutaneously administered to rats at doses of 300 mg/kg/day (equivalent to the recommended maximum human dose based on mg/m2). 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 (equivalent to the recommended maximum human dose based on mg/m2). 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.

Nursing Mothers

It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when spectinomycin is administered to a nursing woman.

Pediatric

Use Safety and effectiveness in the pediatric population have not been established. (See Warnings.)

ADVERSE REACTIONS

The following reactions were observed during the single dose clinical trials: soreness at the injection site, urticaria, dizziness, nausea, chills, fever and insomnia. During multiple dose subchronic tolerance studies in normal human volunteers, the following were noted: a decrease in hemoglobin, hematocrit and creatinine clearance; elevation of alkaline phosphatase, BUN and SGPT. In single and multiple dose studies in normal volunteers, a reduction in urine output was noted. Extensive renal function studies demonstrated no consistent changes indicative of renal toxicity. A few cases of anaphylaxis or anaphylactoid reactions have been reported. If serious allergic reactions occur, the usual agents (epinephrine, corticosteroids, and/or antihistamines) should be available for emergency use. In cases of severe anaphylaxis, airway support and oxygen may also be required.

STORAGE:

Store below 25°C in a cool and dry place.

The reconstituted solution should be used within 24 hour after preparation.

Reconstituted solution should be stored below 25°C.

PRESENTATION:

1Vial of Spectinomycin for injectable suspension USP 2 g + 1 ampoule of Bacteriostatic water for Injection USP 3.2 ml

Manufactured in India:

US Pharma®
(INDIA) Private Limited
Pioneering Excellence. Redefining Quality.
www.uspharma.in