Summary Product Characteristics (SPC)

1. Name of the medicinal product

Generic name: Combipack of Spectinomycin for Injectable Suspension USP &

Bacteriostatic Water for Injection USP

2. Qualitative and quantitative composition

Batch size: 10000 Vials

Sr. No.	Ingredients	Pharmacopoeial Status	Qty (Unit/ml)	Qty/ Batch (Kg)	Function
1.	Spectinomycin Hydrochloride (Sterile) Eq. to Spectinomycin	USP	2000 mg	kg	Active Ingredients

3. Pharmaceutical form

Dosage form: Dry powder for injection

Description: White Colored Powder

4 Clinical particulars

4.1 Therapeutic indications

Spectinomycin is indicated in the treatment of acute gonorrheal urethritis and proctitis in the male and acute gonorrhealcervicitis and proctitis in the female when due to susceptible strains of Neisseria gonorrhoeae. Men and women withknown recent exposure to gonorrhea should be treated as those known to have gonorrhea.

The in vitro susceptibility of Neisseria gonorrhoeae to Spectinomycin can be tested by agar dilution methods

4.2 Posology and method of administration

Intramuscular injections should be made deep into the upper outer quadrant of the gluteal muscle. Adults (men andwomen) -Inject 5ml intramuscularly for a 2 gram dose. This is also the recommended dose for patients being treated after failure of previous antibiotic therapy. Up to 4 grams have been administered in difficult - to - treat cases and in areaswhere antibiotic resistance is known to occur.

Preparation of Drug for Intramuscular Injection

Spectinomycin:reconstitute with 3.2 ml Bacteriostatic Water for Injection. 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. tore prepared suspension at controlled room temperature 150 - 300C and use within 24 hours.

4.3 Interaction with other medicinal products and other forms of interaction

The use of Togozed Sterile Powder is contraindicated in patients previously found hypersensitive to it.

4.4 Pregnancy and lactation

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.

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 losely observed 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

Contains benzyl alcohol. Benzyl alcohol has been reported to be associated with a fatal "Gasping Syndrome" in premature infants and an increased incidence of neurologic and other complications.

Precautions

The usual precautions should be observed with atopic individuals.

The clinical effectiveness of TOGOZED Sterile Powder should be monitored to detect evidence of development of resistance by Neisseria gonorrhoeae. Prescribing Togozed Sterile Powder 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 Togozed Sterile Powder should only be used to treat bacterial infections. They do not treat viral infections (e.g., the common cold). When TOGOZED Sterile Powder 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 Togozed Sterile Powder 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 three- generation 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.

4.5 Undesirable effects

Togozed drug label information in our database does not contain a dedicated section on drug interactions. Please check subsections of WARNINGS AND PRECAUTIONS as well as other sources.

Reporting of suspected adverse reactions: Healthcare professionals are asked to report any suspected adverse reactions via pharmacy and poisons board, Pharmacovigilance Electronic Reporting System (PvERS) https://pv.pharmacyboardkenya.org

4.6 Overdose

Information on overdosage in humans is not available. Hemodialysis has been reported to aid in the removal of intravenously administered spectinomycin from the body. Kusumi R, Metzler C, Fass R; Pharmacokinetics of Spectinomycin in Volunteers with Renal Insuffi ciency, Chemotherapy.

5 Pharmacological properties

5.1 Pharmacodynamic properties

Phamacotherapeutic group: aminocyclitol antibiotics (antibacterials for systemic use)

ATC code: J01XX04

Mechanism of action

Spectinomycin hydrochloride is an inhibitor of protein synthesis in the bacterial cell; the site of action is the 30S ribosomal subunit. In vitro studies have shown spectinomycin hydrochloride to be active against most strains of Neisseria gonorrhoeae (minimum inhibitory concentration <7.5 to 20 mcg/mL). Definitive in vitro studies have shown no cross-resistance of N. gonorrhoeae between spectinomycin hydrochloride and penicillin. The antibiotic is not significantly bound to plasma protein.

TOGOZED Sterile Powder is rapidly absorbed after intramuscular injection. A single, two gram injection produces peak serum concentrations averaging about 100 mcg/mL at one hour; a single, four-gram injection produces peak serum concentrations averaging 160 mcg/Ml at two hours. Average serum concentrations of 15 mcg/mL for the two-gram dose and 31 mcg/mL for the four-gram dose were present eight hours after dosing.

5.2 Pharmacokinetic properties

Streptomycin is not absorbed from the gastrointestinal tract when given orally, and therefore should be administered parenterally for systemic action.

Following i.m. injection of 1 g of the drug, a peak serum level of 25 to 50 µg/mL is reached within 1 hour, diminishing slowly to about 50% after 5 to 6hours. Appreciable Concentrations are found in all organ tissues except the brain. Significant amounts havebeen found in pleural fluid and

tuberculous cavities. Streptomycin passes through the placenta with serum levels in the cord blood similar to maternal levels. Small amounts are excreted in milk, saliva, and sweat.

Streptomycin is excreted rapidly in the urine by glomerular filtration. In patients with normal kidney function, between 29 and 89% of a single 0.6 g dose is excreted within 24 hours. Any reduction of glomerular activity results in decreased excretion of the drug and concurrent rise in serum and tissue levels. Sensitivity Plate Testing: If the KirbyBauer method of disc sensitivity is used, a 10 µg streptomycindisc should give a zone of over 15 mm when tested against a streptomycin-sensitive bacterial Strain.

6 Pharmaceutical particulars

6.1 List of excipients

Benzyl alcohol USP

Water for injections USP

6.2 Incompatibilities

None.

6.3 Shelf life

24 months

6.4 Special precautions for storage

Store at temperature not exceeding 25ºC.

6.5 Nature and contents of container

White Colored Powder filled in 30 ml clear glass vial USP type III having 20 mm Grey butyl rubber stopper and 20 mm flip off seal. Pack Such One Vial With 5 ml Ampoule

in carton with pack insert.

7. Marketing Authorization Holder And Manufacturing Site Addresses

Marketing Authorization Holder:

Zawadi Healthcare Ltd., Kenafric Business Park, Godown C9, Baba Dogo, P.O.Box: 14629-00800, Nairobi, Kenya

8. Marketing Authorization Number

H2010/22641/846

9. Manufacturer

Makcur Laboratories Limited, 46/4-7, Zak, Dehgam: Gandhinagar, India

10. Date of Revision of the Text

17/6/2026