

Temtrix[®] Injection

Ceftriaxone

COMPOSITION:

Temtrix 1 gm IM Injection: Each vial contains Ceftriaxone 1 gm (as Sterile Ceftriaxone Sodium USP) and each ampoule contains 3.5 ml of Lidocaine Hydrochloride BP 1% injection for reconstitution.

Temtrix 1 gm IV: Each vial contains Ceftriaxone 1 gm (as Sterile Ceftriaxone Sodium USP) and each ampoule contains 10 ml Water for Injection BP for reconstitution.

Temtrix 2 gm IV: Each vial contains Ceftriaxone 2 gm (as Sterile Ceftriaxone Sodium USP) and each of two ampoules contains 10 ml Water for Injection BP for reconstitution.

PHARMACOLOGY:

Ceftriaxone is a broad spectrum parenteral third generation cephalosporin antibiotic. The drug is highly resistant to bacterial betalactamases and has a good activity against many gram-positive and gram-negative aerobic and some anaerobic bacteria. It inhibits bacterial cell-wall synthesis in a manner similar to that of penicillin. Once a day dose for many infections is an advantage for this drug.

INDICATION:

Temtrix is indicated for the treatment of the following major infections when caused by susceptible organisms : 1. Urinary tract infections 2. Lower respiratory tract infections particularly pneumonia 3. Gonococcal infections 4. Skin & soft tissue infection 5. Bone & joint infection 6. Bacterial meningitis 7. Serious bacterial infections e.g., septicemia 8. ENT infections 9. Infections in cancer patients 10. Prevention of postoperative infection 11. Perioperative prophylaxis of infections associated with surgery 12. Typhoid fever.

DOSE & ADMINISTRATION:

Adult: It is usually given to adults in a dose of 1 to 2 gm daily as a single dose or in two divided doses depending on the type and severity of infection. In severe infections up to 4gm daily may be given. A single intramuscular dose of 250 mg is recommended for the treatment of uncomplicated gonorrhoea in adult. For surgical prophylaxis in adults, single dose of 1 gm may be administered 0.5 to 2 hours prior to surgery; a 2gm dose is suggested before colorectal surgery.

Children: Suggested doses for infants and children are 50 to 75 mg per kg body weight once daily; for severe infections up to 80 mg per kg body weight daily may be given.

Neonates: In neonates the maximum dose should not exceed 50 mg per kg; intravenous doses in neonates should be given over 60 minutes.

CONTRA-INDICATION:

Patients with known hypersensitivity to cephalosporin group of drugs.

WARNING AND PRECAUTION:

Talk to your doctor or pharmacist before you are given Temtrix if:

1. You have recently received a product that contain calcium.
2. You have recently had diarrhea after taking an antibiotic.
3. You have liver or kidney problem.
4. You have other illness such as haemolytic anaemia.

If you are given Temtrix for a long time you may need to have regular blood test. Temtrix can affect the result of urine for sugar and blood test known as the coombs test.

SIDE EFFECTS:

Well tolerated, side effects are relatively infrequent, usually mild and transient. The most common side effects are gastro-intestinal consisting mainly of loose stool, diarrhoea, nausea, vomiting, stomatitis and glossitis.

USE IN PREGNANCY & LACTATION:

No data are available, so it is probably best to avoid using the drug during pregnancy and by the nursing mothers.

USE IN CHILDREN & ADOLESCENTS:

Children: Ceftriaxone is not recommended for use in neonates with hyperbilirubinaemia. Because ceftriaxone displaces bilirubin from albumin binding sites increasing unconjugated plasma concentration. Concurrent administration of ceftriaxone and calcium-containing solutions is contraindicated.

Adult: Ceftriaxone should not be exceed more than 4 gm daily.

DRUG INTERACTION:

Potentially hazardous Interactions: No impairment of renal function or increased nephrotoxicity has been observed in man after simultaneous administration of ceftriaxone with diuretics or with aminoglycosides. A possible disulfiram-like reaction may occur with alcohol. Other significant interactions: Temtrix doesn't interfere with the protein binding of bilirubin. Simultaneous administration of probenecid doesn't alter the elimination of ceftriaxone. Potentially useful interactions: Experimentally, in vivo, ceftriaxone has been shown to enhance bacterial killing by human neutrophils.

ADVERSE DRUG REACTION:

Risk of convulsion and involuntary movements.

Convulsion (Nervous system disorder): Allergic reactions, drug fever, serum sickness-like reaction, renal dysfunction, toxic nephropathy, reversible hyperactivity, hypertonia, hepatic dysfunction including cholestasis, aplastic anemia, hemorrhage and super infection.

Check tolerability of patients with test dose before using. Take at least 2 to 4 minutes during administration.

OVERDOSE:

In the case of overdose, The symptoms of nausea, vomiting and diarrhea can occur. Ceftriaxone concentration can not be reduced by hemodialysis or peritoneal dialysis. There is no specific antidote. Treatment should be symptomatic.

STORAGE:

Store below 25°C, protected from light & moisture. Use reconstituted solutions immediately. Reconstituted solutions are stable for 6 hours at room temperature and for 24 hours at 2°-8°C. It should not be mixed in the same syringe with any drug other than 1% Lidocaine Hydrochloride injection BP (For IM injection only)

PACKING:

Temtrix is supplied as a sterile crystalline powder in glass vial.

Temtrix 1 gm IM Injection: Blister Pack of 1 vial containing 1 gm Ceftriaxone (as Sterile Ceftriaxone Sodium USP) accompanied by one ampoule of 3.5 ml Lidocaine 1% BP injection.

Temtrix 1gm IV Injection: Blister Pack of 1 vial containing 1gm Ceftriaxone (as Sterile Ceftriaxone Sodium USP) accompanied by one ampoule of 10 ml Water For Injection BP

Temtrix 2 gm IV Injection: Blister Pack of 1 vial containing 2 gm Ceftriaxone (as Sterile Ceftriaxone Sodium USP) accompanied by two ampoules of 10 ml Water for Injection BP.



Manufactured by
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