

Summary of Product Characteristics

1. Name of the medicinal product:

Epicephin[®] 1 gram vial

2. Qualitative and quantitative composition:

Active Ingredient:

Ceftriaxone (as sodium salt).....1 g.

For full list of excipients, see section 6.1.

3. Pharmaceutical form:

Yellowish powder giving yellowish orange solution after reconstitution.

4. Clinical particulars:

4.1 Therapeutic indications:

Epicephin[®] is used in the treatment of infections due to susceptible organisms, especially serious infections, including:

- Bacterial septicemia.
- Meningitis.
- Intra-abdominal infections.
- Bone and joint infections.
- Skin and soft tissue infections.
- Lower respiratory tract infections.
- Urinary tract infections (complicated and uncomplicated).
- Pelvic inflammatory disease.
- Uncomplicated gonorrhoea (cervical/urethral and rectal).
- Surgical infection prophylaxis.

4.2 Posology and method of administration:

Administer IM/IV. Continue for ≥ 2 days after signs and symptoms of infection have disappeared. Usual duration is 4 to 14 days; in complicated infections, longer therapy may be required. For *S. pyogenes*, continue for ≥ 10 days.

Adults:

Usual daily dose is 1 – 2 g once daily (or in equally divided doses twice daily) depending on the type and severity of the infection. Do not exceed total daily dose of 4 g.

Uncomplicated Gonococcal Infections: Give a single IM dose of 250 mg.

Surgical Infection Prophylaxis: Give a single 1 g dose IV 0.5 – 2 hours before surgery.

Meningitis/Endocarditis: 1 – 2 g IV every 12 hours for 10 to 14 days (in meningitis) or for ≥ 4 weeks (in endocarditis).

Children:

To treat serious infections other than meningitis, administer 50 – 75 mg/kg/day (not to exceed 2 g) in divided doses twice daily (every 12 hours).

Meningitis: Initial therapeutic dose: 100 mg/kg/day (not to exceed 4 g). Thereafter, a total daily dose of 100 mg/kg/day (not to exceed 4 g/day) is recommended. It may be given in a dose once daily or in equally divided doses twice daily (every 12 hours). Usual duration is 7 to 14 days.

Skin and Skin structure infections: Give 50 – 75 mg/kg once daily or in equally divided doses twice daily (every 12 hours), not to exceed 2 g.

Renal/hepatic function impairment:

No dosage adjustment is necessary; however, monitor blood levels.

In patients with both hepatic dysfunction and significant renal disease, the dose should not

exceed 2 g/day without closely monitoring serum concentrations.

Treatment Schedules for Chancroid, Gonorrhea and Acute Pelvic Inflammatory Disease:

Chancroid (*Haemophilus durcreyi* infection): 250 mg IM as a single dose.

Gonococcal infections:

Uncomplicated: 125 mg IM in a single dose plus 1 g azithromycin in single oral dose or 100 mg doxycycline twice daily for 7 days.

Conjunctivitis: 1 g IM as a single dose.

Disseminated: 1 g IM or IV every 24 hours.

Reconstitution of **Epicephin®**:

For IM injection: **Epicephin®** 250 mg or 500 mg is dissolved in 2 ml, and **Epicephin®** 1 g in 3.5 ml, of 1% lidocaine solution.

For IV injection: **Epicephin®** 250 mg or 500 mg is dissolved in 5 ml, and **Epicephin®** 1 g in 10 ml, of sterile water for injection.

For IV infusion: **Epicephin®** 2 g are dissolved in 20 ml of sterile water for injection or in one of the following calcium-free infusion solutions: Sodium chloride 0.9%; Sodium chloride 0.45% + Dextrose 2.5%; Dextrose 5%; Dextrose 10%; Levulose 5%; Dextran 6% in dextrose.

After reconstitution, further dilute to 50 ml or 100 ml volume with the appropriate IV diluent.

-Epicephin® should be given by deep IM injection, or by slow IV injection over at least 2 – 4 minutes, or by intermittent IV infusion over at least 30 minutes.

-If more than 1 g is to be injected intramuscularly then the dose should be divided between more than one site.

-For IM injection, 1% lidocaine solution is used as solvent. IM injection without lidocaine solution is painful.

-For IV injection, sterile water for injection is used as solvent. Lidocaine solution should never be used.

4.3 Contraindications:

-A known hypersensitivity to cephalosporins or related antibiotics.

-Neonates with jaundice.

4.4 Special warnings and precautions for use:

-Calcium-containing solutions or products must not be administered within 48 hours of last administration of ceftriaxone because of the risk of precipitation of Ceftriaxone-Calcium salt in term of newborns.

4.5 Interaction with other medicinal products:

-Aminoglycosides may have additive effect.

-**Epicephin®** may have the potential to increase the effect of anticoagulants.

-Alcohol use may cause disulfiram-like reaction.

-Unlike many cephalosporins, probenecid does not affect renal excretion of **Epicephin®**.

4.6 Fertility, pregnancy and lactation:

Epicephin® vials should be used with caution, and only if clearly needed, in pregnancy and lactation; only if the potential benefit justifies the potential risk to the fetus or to the breast-fed infant, respectively.

Fertility:

Reproductive studies have shown no evidence of adverse effects on male or female fertility.

4.7 Effects on ability to drive and use machines:

Patients should be cautious when driving or operating machinery.

4.8 Undesirable effects:

Epicephin® is generally well tolerated. The most common side effects are local reactions: inflammatory irritation with IV administration, and pain after IM injection. Other side effects

may include hypersensitivity reactions, such as rash, pruritus; headache, dizziness; effects on blood picture; transient elevation in serum liver enzyme levels (SGOT and SGPT); nausea, vomiting, diarrhoea, and pseudomembranous colitis.

Reporting of suspected adverse reactions:

Healthcare professionals are requested to report any suspected adverse reactions via national Pharmacovigilance Electronic Reporting Systems' to the respective national regulatory authorities.

4.9 Overdose:

There is no specific antidote. Treatment of overdose should be symptomatic.

5. Pharmacological properties:

5.1 Pharmacodynamic properties:

Epicephin® is a third generation cephalosporin broad spectrum antibiotic which acts by inhibition of cell wall synthesis. It has greater bactericidal activity than first or second generation cephalosporins against Gram-negative bacteria. It is highly stable in the presence of beta-lactamases produced by certain bacteria. It is generally effective against many pathogens including: *H. influenzae*, *Moraxella* sp., *Neisseria meningitidis* and gonorrhoeae, *E. coli*, *Proteus mirabilis* and *vulgaris*, *Klebsiella* sp., *Salmonella* sp., *Shigella* sp., *Morganella morganii*, *Providentia* sp., *Enterobacter* sp., *Serratia* sp., *Yersinia* sp., *H. ducreyi*, *Pseudomonas aeruginosa* (some strains are resistant); *Staphylococcus aureus* and *epidermidis*, *Streptococcus pneumoniae*, *pyogenes*, *viridians* and *bovis*.

Epicephin® is also active against some anaerobic bacteria such as *Bacteroides* sp., *Peptococcus* species, *Peptostreptococcus* species, and *Clostridium* species (except *C. difficile*).

5.2 Pharmacokinetic properties:

Ceftriaxone mean peak plasma concentrations of about 40 and 80 µg/ml have been reported 2 hours after IM injection of 0.5 and 1 g respectively. Ceftriaxone is 85 – 95% bound to plasma protein. Plasma half-life of ceftriaxone varies between 6 and 9 hours; it may be prolonged in neonates and also in severe renal impairment especially when there is also hepatic impairment.

Ceftriaxone is widely distributed in body tissues and fluids. It crosses inflamed meninges, generally achieving therapeutic concentrations in the CSF. High concentrations are achieved in bile.

About 40 – 65% of a dose of ceftriaxone is excreted unchanged in the urine; principally by glomerular filtration; the remainder is excreted in bile and is ultimately found in feces as unchanged drug and inactive metabolites.

5.3 Preclinical safety data:

None

6. Pharmaceutical particulars:

6.1 List of excipients:

No Excipients.

6.2 Incompatibilities:

-Aminoglycosides may have additive effect.

-**Epicephin®** may have the potential to increase the effect of anticoagulants.

-Alcohol use may cause disulfiram-like reaction.

-Unlike many cephalosporins, probenecid does not affect renal excretion of **Epicephin®**.

6.3 Shelf life:

3 years.

6.4 Special precautions for storage:

Store at temperature below 30 °C.

6.5 Nature and contents of container:

Epicephin® 1 g: 1 vial + solvent of sterile water for injection.

6.6 Special precautions for disposal and other handling:

N.A

7. Marketing authorization holder & manufacturing site address.

EGYPTIAN INT. PHARMACEUTICAL INDUSTRIES CO. EIPICO

10th OF RAMADAN CITY, INDUSTRIAL AREA B1, P.O. BOX: 149 TENTH, EGYPT.

8. Marketing authorization number

20466

9. Date of first Registration/ Renewal of the Registration

April 2010.

10. Date of revision of the text:

31/03/2026