RECOCEPT 250 / 500 / 1000 (1G) INJECTION

COMPOSITION

RECOCEPT-250 Injection
Each vial contains:
Ceftriaxone Sodium IP equivalent to
Ceftriaxone ..... 250 mg
Supplied with 5 ml Sterile Water for Injection IP
RECOCEPT – 500 Injection
Each vial contains:
Ceftriaxone Sodium IP equivalent to
Ceftriaxone ..... 500 mg
Supplied with 5 ml Sterile Water for Injection IP
RECOCEPT- 1g Injection
Each vial contains:
Ceftriaxone Sodium IP (Sterile) equivalent to
Ceftriaxone ..... 1,000 mg
Supplied with 10 ml Sterile Water for Injection IP

INDICATIONS

Before instituting treatment with **RECOCEPT Injection**, appropriate specimens should be obtained for isolation of the causative organism and for determination of its susceptibility to the drug. Therapy may be instituted prior to obtaining results of susceptibility testing.
To reduce the development of drug-resistant bacteria and maintain the effectiveness of **Recocept** , it should be used only to treat or prevent infections that are proven or strongly suspected to be caused by susceptible bacteria.
RECOCEPT Injection (ceftriaxone) is indicated for the treatment of the following infections when caused by susceptible organisms:
Lower Respiratory Tract Infectionscaused by *Streptococcus pneumoniae, Staphylococcus aureus, Haemophilus influenzae, Haemophilus parainfluenzae, Klebsiella pneumoniae, Escherichia coli, Enterobacter aerogenes, Proteus mirabilis* or *Serratia marcescens.*
Acute Bacterial Otitis Media caused by *Streptococcus pneumoniae, Haemophilus influenzae*(including beta-lactamase-producing strains) or *Moraxella catarrhalis* (including beta-lactamase-producing strains).
Skin and Skin Structure Infections caused by *Staphylococcus aureus*, *Staphylococcus epidermidis*, *Streptococcus pyogenes*, Viridans group streptococci, *Escherichia coli, Enterobacter cloacae, Klebsiella oxytoca, Klebsiella pneumoniae, Proteus mirabilis, Morganella morganii,* Pseudomonas aeruginosa, Serratia marcescens, Acinetobacter calcoaceticus, Bacteroides fragilis** or *Peptostreptococcus* species.
Urinary Tract Infections(complicated and uncomplicated)caused by *Escherichia coli, Proteus mirabilis, Proteus vulgaris, Morganella morganii* or *Klebsiella pneumoniae*.
Uncomplicated Gonorrhoea (cervical/urethral and rectal) caused by *Neisseria gonorrhoeae*, including both penicillinase-and non penicillinase-producing strains, and pharyngeal gonorrhoea caused by non-penicillinase-producing strains of *Neisseria gonorrhoeae*.
Pelvic Inflammatory Disease caused by *Neisseria gonorrhoeae*. **RECOCEPT Injection**(ceftriaxone), like other cephalosporins, has no activity against *Chlamydia trachomatis*. Therefore, when cephalosporins are used in the treatment of patients with pelvic inflammatory disease and*Chlamydia trachomatis* is one of the suspected pathogens, appropriate anti-chlamydial coverage should be added.
Bacterial Septicaemia caused by *Staphylococcus aureus, Streptococcus pneumoniae, Escherichia coli, Haemophilus influenzae* or *Klebsiella pneumoniae*.
Bone and Joint Infections caused by *Staphylococcus aureus, Streptococcus pneumoniae, Escherichia coli, Proteus mirabilis, Klebsiella pneumoniae* or *Enterobacter* species.
Intra-Abdominal Infections caused by *Escherichia coli, Klebsiella pneumoniae, Bacteroides fragilis, Clostridium* species (**Note:** most strains of *Clostridium difficile* are resistant) or*Peptostreptococcus* species.

Meningitis caused by *Haemophilus influenzae, Neisseria meningitides* or *Streptococcus pneumoniae*. **RECOCEPT Injection** (ceftriaxone) has also been used successfully in a limited number of cases of meningitis and shunt infection caused by *Staphylococcus epidermidis** and*Escherichia coli*.*
*Efficacy for this organism in this organ system was studied in fewer than ten infections.

Surgical Prophylaxis

The pre-operative administration of a single 1 gm dose of **RECOCEPT Injection** (ceftriaxone) may reduce the incidence of post-operative infections in patients undergoing surgical procedures classified as contaminated or potentially contaminated (e.g., vaginal or abdominal hysterectomy or cholecystectomy for chronic calculous cholecystitis in high-risk patients, such as those over 70 years of age, with acute cholecystitis not requiring therapeutic antimicrobials, obstructive jaundice or common duct bile stones) and in surgical patients for whom infection at the operative site would present a serious risk (e.g., during coronary artery bypass surgery).

DOSAGE AND ADMINISTRATION

RECOCEPT Injection (ceftriaxone) may be administered by the I.V. or I.M. route.
RECOCEPT Injection (ceftriaxone) must not be administered simultaneously with calcium-containing I.V. solutions, including continuous calcium-containing infusions such as parenteral nutrition via a Y-site. However, in patients other than neonates, **RECOCEPT Injection**(ceftriaxone) and calcium-containing solutions may be administered sequentially of one another if the infusion lines are thoroughly flushed between infusions with a compatible fluid.

Directions for Use

I.M. Administration

Reconstitute **RECOCEPT Injection** (ceftriaxone) powder with the appropriate diluents.
Inject diluents into vial, shake vial thoroughly to form solution. Withdraw entire contents of vial into syringe to equal total labelled dose.
After reconstitution, each 1 mL of solution contains approximately 250 mg or 350 mg equivalent of ceftriaxone according to the amount of diluents indicated below. If required, more dilute solutions could be utilized.
As with all I.M. preparations, **RECOCEPT Injection** (ceftriaxone) should be injected well within the body of a relatively large muscle; aspiration helps to avoid unintentional injection into a blood vessel.

Vial Dosage Size	Amount of Diluent to be Added
250 mg	0.9 mL
500 mg	1.8 mL
1 gm	3.6 mL

I.V. Administration

RECOCEPT Injection (ceftriaxone) should be administered by I.V. infusion over a period of 30 minutes. Concentrations between 10 mg/mL and 40 mg/mL are recommended; however, lower concentrations may be used if desired. Reconstitute vials with the appropriate I.V. diluents.

Vial Dosage Size	Amount of Diluents to be Added
250 mg	2.4mL
500 mg	4.8 mL
1 gm	9.6 mL

After reconstitution, each 1 mL of solution contains approximately 100 mg equivalent of ceftriaxone. Withdraw entire contents and dilute to the desired concentration with the appropriate I.V. diluents.

PACKAGING INFORMATION

RECOCEPT-250 Injection ..... Vial of 10 ml with 5 ml of Sterile Water for Injection
RECOCEPT-500 Injection ..... Vial of 10 ml with 5 ml of Sterile Water for Injection
RECOCEPT -1 g Injection ..... Vial of 15 ml with 10 ml of Sterile Water for Injection